

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
EASTERN DIVISION-RIVERSIDE

HONORABLE VIRGINIA A. PHILLIPS, JUDGE PRESIDING

UNITED STATES OF AMERICA, )  
 )  
Plaintiff, )  
 )  
V. ) DOCKET NO. EDCR 08-172(B)VAP  
 )  
VINOD CHANDRASHEKM PATWARDHAN, )  
 )  
Defendant. )  
\_\_\_\_\_ )

REPORTER'S TRANSCRIPT OF JURY TRIAL PROCEEDINGS  
Riverside, California  
Wednesday, April 29, 2009

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License No. 8701  
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United States District Court  
3470 Twelfth Street  
Riverside, California 92501

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1 WEDNESDAY, APRIL 29, 2009, RIVERSIDE, CALIFORNIA

2 ---o0o---

3 THE COURT: Mr. Widman, or is it Mr. Behnke?

4 MR. BEHNKE: Yes, Your Honor.

5 THE COURT: You may proceed.

6 MR. BEHNKE: Ladies and gentlemen, the Government  
7 expects that over the next week and a half to two weeks or so  
8 the evidence is going to show that this is a case about  
9 greed. It's a case about money.

10 The Government expects that the evidence is going  
11 to show the defendant smuggled the drugs from these foreign  
12 countries into the United States and gave the drugs to his  
13 patients because the drugs were cheaper. The unapproved  
14 drugs in India, Honduras, Panama, and the Philippines were  
15 much cheaper than approved drugs in the United States.

16 After smuggling the drugs into the United States  
17 the defendant administered the drugs to his patients. He  
18 didn't tell his patients exactly what they were getting, and  
19 he billed the patients, their insurance companies, and  
20 Medicare as though they were receiving the approved United  
21 States drugs, the FDA-approved drugs. By doing so, he  
22 realized a substantial profit.

23 You will learn that the defendant has been a  
24 practicing physician in this state for over 25 years. Among  
25 other things, he administers chemotherapy and cancer

1 treatments to cancer patients at an office in Upland,  
2 California.

3 During the trial you will see some photographs of  
4 the office. This is the exterior of the office. You see the  
5 defendant's name above the door. Here's a shot of the inside  
6 of the office, waiting area. And you see here a photograph  
7 of a refrigerator where some of the cancer drugs were stored  
8 in this room. The employees that work for the defendant will  
9 refer to this as the lab area.

10 And you see in this photograph a photograph of the  
11 chemotherapy room. In this room patients would come, they  
12 would sit in these chairs, sometimes for several hours, and  
13 by IV treatment they would receive chemotherapy drugs. You  
14 will learn that that happened on Tuesdays and Thursdays in  
15 the defendant's office.

16 Now, normally, the cabinets and other doors that  
17 you see in this photograph are not open. You'll learn that  
18 this photograph was taken during a search that was conducted  
19 by federal agents which is why all the doors and cabinets are  
20 open in the picture.

21 The photos depict what might be considered an  
22 ordinary neighborhood medical office. However, as you will  
23 learn, when patients went into this office to receive  
24 treatment, to receive help for their cancer and other  
25 ailments, unbeknownst to them, many of the patients that went

1 in were receiving unapproved medications from outside the  
2 United States that had been smuggled into the country.

3 During the course of the trial you're going to hear  
4 from several employees that worked in this medical office  
5 with the defendant. Some of the names you're going to hear  
6 during the course of the trial include Norma Franco, Mayra  
7 Jaurequi, Jessica Perez, Mindy Funk, and possibly even a few  
8 others.

9 In addition to the medical office in Upland,  
10 defendant also had a medical office in Chino. You'll learn  
11 that the patients that the defendant saw, in terms of  
12 billing, fell into three categories. Some of the patients  
13 that he saw were considered cash patients. Those were  
14 patients that paid cash for services. Other patients had  
15 private insurance. Those patients would see the defendant,  
16 receive treatments, the insurance company would be billed,  
17 and oftentimes the patients had to pay a co-pay to the  
18 defendant. And also some of the patients that the defendant  
19 saw received Medicare benefits. And for those patients their  
20 treatments we're billed to the federal government through  
21 Medicare.

22 For many years defendant obtained much of the drugs  
23 that he used at his practice from outside the United States.  
24 The drugs that he obtained outside the United States came  
25 largely from India and Honduras, but you will also hear about

1 some drugs coming from Panama and some drugs coming from the  
2 Philippines.

3 Over the course of several years defendant and  
4 several of his -- excuse me -- several co-conspirators would  
5 go outside the United States. They traveled to India. They  
6 traveled to Honduras. They would physically pick up the  
7 drugs, conceal the drugs in their luggage, and bring them  
8 into the United States. They would bring them to the office  
9 and then use the drugs in their practice.

10 Most of the drugs that were used in the practice  
11 were obtained in that fashion. However, you will also learn  
12 that some of the drugs that the defendant used in his  
13 practice were, in fact, FDA-approved drugs. The employees  
14 and the defendant would keep track of the drug supplies in  
15 the office, and when the drugs were running low, if the  
16 defendant or one of the other individuals did not have a  
17 foreign trip coming up, the defendant would tell his  
18 employees to purchase FDA-approved drugs usually from a  
19 company named OTN.

20 When the drugs would arrive from OTN, you'll learn  
21 that they were shipped to the defendant's office by Federal  
22 Express in a container along with dry ice. When the drugs  
23 arrived in the defendant's office from the foreign countries,  
24 they were personally transported by either the defendant or  
25 one of his employees.

1           A couple of the names that you're going to hear and  
2 actually witnesses that you will hear from during this trial  
3 are Jessica Young and Velma Yep. And there is another  
4 individual that the evidence will show brought drugs back  
5 into the United States for the defendant, a dentist by the  
6 name of Dr. Mhaskar.

7           Even though most of the drugs that were used in the  
8 defendant's practice were the unapproved foreign drugs, you  
9 will learn that the defendant and his staff when dealing with  
10 the drugs, when dealing with patients, and even when dealing  
11 with other physicians, always referred to FDA-approved  
12 drugs.

13           I'll give you an example. One of the drugs that  
14 you're going to hear referred to a lot in this case that came  
15 from India is a drug by the name of Docetax. Docetax is a  
16 chemotherapy drug that has an active ingredient, Docetaxel.  
17 In the United States the FDA has approved another drug  
18 product by the name of Taxotere that uses the same active  
19 ingredient. The defendant would go to India, purchase the  
20 Docetax, bring it into the country, administer the Docetax to  
21 his patients but referred to it as Taxotere. In fact, you  
22 will see other photographs of the inside of that refrigerator  
23 that you saw earlier. There's a bin in there that has a  
24 label on it that says Taxotere. Inside that bin they stored  
25 Docetax.



1           When patients would receive chemotherapy they would  
2 write on the IV drip bag the name of the drug that the  
3 patient was receiving. If the patient was receiving Docetax,  
4 the name on the bag would be Taxotere. The insurance  
5 companies and Medicare would be billed for Taxotere. The  
6 patients, Medicare, were not told what was actually being  
7 administered was Docetax.

8           One of the patients that was treated by the  
9 defendant during this period was a woman by the name of  
10 Veronica Lin. Veronica Lin was treated by defendant from  
11 late 2005 until 2007. Her daughter, Kathy Walton, oversaw  
12 Ms. Lin's care and paid the bills for Ms. Lin. You're going  
13 to hear from Ms. Walton during the course of this trial. You  
14 will hear that her mother, Ms. Lin, went to the defendant's  
15 office many times to receive chemotherapy treatment. In  
16 addition to that, the defendant gave Ms. Walton injections or  
17 shots to take home to administer to her mother at home.

18           Ms. Lin had private insurance. Ms. Walton on  
19 behalf of her mother paid co-pays to the defendant for her  
20 care. Included in the co-pays were substantial co-pays for  
21 these take-home injections. She was told and, in fact,  
22 you'll see receipts that she received from the defendant's  
23 office, that the take home injections were an FDA-approved  
24 drug. However, what she was actually receiving was  
25 unapproved drugs that the defendant had smuggled into the

1 country from India.

2           During the course of this conspiracy the defendant  
3 and his co-conspirators smuggled more than a million dollars  
4 worth of drugs into the United States. The drugs that they  
5 brought into the United States were illegally smuggled into  
6 the country. The drugs were misbranded and they were not  
7 approved by the FDA for distribution in the United States;  
8 therefore, importation of those drugs is prohibited. And you  
9 will learn from Dr. Charles Lee, who works for the FDA, that  
10 these drugs are, in fact, unapproved. He will also explain  
11 to you that the labeling on these drugs was inadequate.

12           And you'll also learn what it means for a drug to  
13 become approved. The FDA has in place a rigorous procedure  
14 where drug companies, when they want to seek approval to  
15 distribute a drug in the United States, they have to submit  
16 an application to the FDA, and the FDA then inspects the drug  
17 itself, the ingredients that are in the drug, the way the  
18 drug interacts with the human body. They even inspect the  
19 plant and the facilities where the drug is produced before  
20 they approve the product. None of the drugs that the  
21 defendant was smuggling into the country went through this  
22 process. As a result, they can't lawfully be distributed.

23           So the way that the defendant got the drugs into  
24 the country so that he could administer them to his patients  
25 was by smuggling them, by deceiving Customs. The drugs would

1     come into the country in small gym bags, typically, but you  
2     will also learn that sometimes the drugs were contained  
3     inside department store gift boxes. The drugs would be  
4     concealed inside luggage, the checked luggage. And when the  
5     defendant, Jessica Young, Velma Yep, would enter the country  
6     and pass through Customs, they wouldn't declare the  
7     merchandise that they were importing, specifically the drugs.  
8     Once the drugs were admitted into the country, he would  
9     administer them to his patients.

10             And, again, why go to this trouble? Why go to the  
11     trouble of going overseas, going to Honduras and physically  
12     bringing these drugs back? Again, the evidence will show  
13     because of the money.

14             Jessica Young is going to testify for you that not  
15     only did she make many trips to Honduras and bring back many  
16     drugs for the defendant, but that she kept detailed records  
17     of all of these transactions. Jessica Young during this time  
18     was the defendant's office manager, worked in the defendant's  
19     medical practice, and she kept detailed records of her trips,  
20     of the defendant's trips, and of the trips made by Velma Yep  
21     and Dr. Mhaskar.

22             One of the things that she kept track of was cost  
23     comparisons. And the records that she kept show that  
24     purchasing the drugs outside the country, these unapproved  
25     drugs, resulted in substantial savings. Some of her records

1 show that they were saving 60 percent or more by buying the  
2 drugs outside the country.

3 When you extrapolate that to over a million dollars  
4 worth of drugs purchased outside the country, that results in  
5 substantial savings which translates to direct profits for  
6 the defendant, because, again, all of these drugs were billed  
7 as though they were the approved United States drugs.

8 You will hear testimony also from Customs and FDA  
9 employees about the procedures that travelers go through when  
10 they enter the country. You will learn that travelers  
11 arriving in this country on international flights are given a  
12 declaration form that they have to fill out before they pass  
13 through Customs. This is the front page of such a Customs  
14 declaration.

15 THE COURT: You're going to need to focus in on  
16 it.

17 MR. BEHNKE: I'll zoom in.

18 One of the questions on the form -- we can't read  
19 the entire thing on the screen, but one of the questions on  
20 the form says, "Residents: The total value of all goods  
21 including merchandise I or we have purchased or acquired  
22 abroad and are bringing into the U.S. is." And then there's  
23 a blank that the traveler is supposed to fill in.

24 And then the back side of the form, again, you  
25 can't read the entire thing on the screen, so I'll read it

1     for you. "U.S. residents: Declare all articles that you  
2     have acquired abroad and are bringing into the United  
3     States." And then a little farther down the form are blanks  
4     where you describe the article and list the value.

5             After filling this form out, the traveler meets  
6     with the Customs agent and the Customs agent checks the  
7     passport, checks the Customs declaration form. And then,  
8     after passing that point, the traveler goes to collect their  
9     checked baggage.

10            If a traveler declares on this form that they have  
11     commercial merchandise or merchandise valued at over \$2,000,  
12     Customs will require what they call a formal entry. A formal  
13     entry has several requirements that go with it, including  
14     posting of a bond, but for this purpose what's important  
15     about the formal entry is when formal entries are made of  
16     commercial merchandise, for instance, merchandise that's  
17     going to be sold in the United States, there's a permanent  
18     record made of that entry. If the traveler makes a formal  
19     entry, that gets entered into a database and there's  
20     permanent record of it.

21            You'll learn that defendant made approximately  
22     12 to 13 trips to India, brought drugs back on those trips,  
23     thousands of dollars worth of drugs. Some of the trips that  
24     the defendant made to India he transported back in his  
25     luggage 49, \$50,000 or more worth of drugs. You'll learn

1 that that amount of drugs usually translated into about a  
2 three-month supply for his medical practice. Again, the  
3 drugs were administered to his patients back in his office.  
4 There's no record of any formal entries by the defendant.

5 Now, you will also learn that after the travelers  
6 passed through Customs some passengers are selected for  
7 secondary inspection. When passengers are selected for  
8 secondary inspection, they collect their checked luggage and  
9 then go to the secondary inspector. You will learn during  
10 the course of this conspiracy, I believe you will learn that  
11 it was in 2005, the defendant, on one of his trips when he  
12 had drugs in his luggage, was selected for secondary  
13 inspection. When a passenger is selected for secondary  
14 inspection, there is a permanent record made of that fact.  
15 You will see a copy of that record.

16 During the course of the trial you will hear  
17 testimony from the Customs inspector that did that secondary  
18 inspection in 2005. What you will learn from him is, first,  
19 that that inspector doesn't specifically remember this  
20 traveler from several years ago. But what you will learn is  
21 that if the inspector during the secondary inspection  
22 encountered thousands of dollars worth of drugs that were  
23 going to be sold to patients here in the United States, he  
24 would have required a formal entry and there would be a  
25 permanent record of that. There's no such record following

1     that secondary inspection. The only notation in the  
2     secondary inspection record is something to the effect of  
3     passenger is a doctor visiting family for one month in  
4     India.

5             And you will also learn that when a passenger goes  
6     through secondary inspection, it's at the discretion of the  
7     Customs agent doing the inspection to determine how thorough  
8     that inspection is. Sometimes some of the bags are searched.  
9     Sometimes all of the bags are searched. It's up to the  
10    individual inspector.

11            As I indicated earlier, another witness that you're  
12    going to hear from is Jessica Young. You're going to learn  
13    that Jessica Young has pleaded guilty to introducing  
14    misbranded drugs into interstate commerce. And pursuant to  
15    that plea she has agreed to testify against her former boss  
16    in this proceeding. She is going to explain to you how the  
17    practice worked. She is going to explain to you how she  
18    personally smuggled hundreds of thousands of dollars worth of  
19    drugs from Honduras to defendant's medical practice. Some of  
20    the transactions that Jessica Young was involved with  
21    involved \$100,000 or more worth of drugs on each trip.

22            She will tell you that when she brought these drugs  
23    in on the defendant's behalf, she kept the drugs concealed in  
24    her luggage. When she was presented with the Customs  
25    declaration form each time she came in, she left it blank.

1 She didn't declare the drugs. She will explain to you that  
2 she did that, she kept the drugs concealed, she didn't  
3 declare the drugs, because she did not want Customs to find  
4 the drugs.

5 She will even explain to you that to better ensure  
6 that Customs would not find the drugs, on some of the trips  
7 she would hide the drugs inside Nordstrom gift boxes. And  
8 then on the box she would put a label that said donuts or  
9 something to that effect. She will tell you that she did so  
10 so that Customs wouldn't look inside, wouldn't find the  
11 drugs.

12 You will also hear testimony from another one of  
13 the defendant's former employees named Velma Yep. Velma Yep  
14 also worked for the defendant for many years, and she, too,  
15 has pleaded guilty to introducing misbranded drugs into  
16 interstate commerce. She, too, has agreed to come in and  
17 testify for you against her former boss.

18 She is going to explain to you that several years  
19 ago she was on vacation in Canada and the defendant called  
20 her up while she was in Canada and asked her to bring drugs  
21 back into the United States from Canada. She will tell you  
22 that she agreed and got off the phone, but that she actually  
23 didn't go get the drugs and bring them in because she didn't  
24 feel right about it. So she came back, went to work and told  
25 the defendant, "I looked for the drugs. Couldn't find



1       them."

2               Then in 2008 she was going on a trip to the  
3       Philippines. Defendant contacted her, I believe she will  
4       tell you by e-mail, and asked her when she goes to the  
5       Philippines to bring some drugs back. She will explain to  
6       you that she wanted to do something for him, so she did. He  
7       requested several different drugs. She will explain to you  
8       that one of those drugs, I believe the name you will hear is  
9       Zofran, she purchased in the Philippines, concealed in her  
10      luggage and brought back to the defendant's practice.

11             She, too, will tell you that when she passed  
12      through Customs she didn't declare the drugs that she had in  
13      her possession, even though it was valued at thousands of  
14      dollars, and that she brought them to the medical practice to  
15      be used at the medical practice. Again, she will explain to  
16      you that she didn't declare them on the Customs form because  
17      she didn't want Customs to find them.

18             Now, in March of 2008, defendant's employees in his  
19      medical practice became uncomfortable with the foreign  
20      medications that were there. You will learn that a shipment  
21      of drugs from India arrived at that time in a gym bag. An  
22      employee, Norma Franco, was sent to inventory the drugs in  
23      the gym bag. And you will learn that over the years Norma  
24      and Mayra Jaurequi -- excuse me, I can't pronounce it  
25      correctly -- Jaurequi, were typically tasked with

1 inventorying the drugs that came in in the gym bags. In  
2 March of 2008, again, Norma was sent to count the drugs in  
3 the gym bag, count the drugs to make sure the defendant was  
4 getting what he paid the Indian distributor for.

5 Norma Franco told another employee, a nurse  
6 practitioner by the name of Mindy Funk, who you will also  
7 hear from, about the drugs in the gym bag. Mindy Funk looked  
8 at the drugs in the gym bag and immediately recognized that  
9 there was a problem with those drugs, immediately recognized  
10 that they should not be there. And she told other employees  
11 in the office to take pictures of the drugs and take pictures  
12 of the invoice that was with the drugs. Forgive me if this  
13 doesn't come out very well, it's a bad black and white, but  
14 you'll see this photograph of the drugs in the gym bag. This  
15 is a copy of the photograph that was taken in March of 2008  
16 by the defendant's employees.

17 In addition to taking the photograph of the drugs,  
18 the employees also began taking samples of the foreign drugs  
19 from the practice and taking them home so that they could  
20 turn them over to the authorities. And eventually, one of  
21 his employees, Jessica Perez, did, in fact, call the police.  
22 She called the authorities. It eventually was referred to  
23 the FDA, and the FDA investigation began.

24 In July 2008, FDA agents and other federal agents  
25 went to the defendant's office with a search warrant. When

1 they went to the office with a search warrant, they found the  
2 unapproved foreign drugs. They found records pertaining to  
3 the drugs and other documents that you're going to see during  
4 the course of this trial.

5 When they went there to do the search in July of  
6 2008, they also interviewed the defendant. You will learn  
7 that the defendant arrived at the office while the search was  
8 going on. The agents greeted him. They went into his  
9 private office in the medical office that you saw the  
10 pictures of.

11 Inside defendant's private office they interviewed  
12 him. They explained to him why they were there. They told  
13 him that they were their conducting a search related to an  
14 investigation of his bringing unapproved drugs into the  
15 country from India.

16 They showed him a copy of the search warrant which  
17 contained a factual affidavit explaining the investigation.  
18 You will learn that the defendant glanced at the search  
19 warrant and set it aside. The agents asked the defendant if  
20 he had, in fact, been bringing unapproved drugs into the  
21 country from India, and he said that he had. They asked him  
22 how many times he had done it, and he told them he had done  
23 it 12 or 13 times.

24 Then at that point the defendant put his head down  
25 on the desk and said something to the effect of, "I'm less

1     than a man," and then told the agents that he felt sick and  
2     wanted to go home. The agents ended the interview and got  
3     one of the defendant's employees to drive him home.

4             The evidence will show that over the course of this  
5     conspiracy the defendant made a great deal of money by  
6     bringing the unapproved drugs into the United States and  
7     giving them to his patients and billing his patients,  
8     insurance, and Medicare for those drugs.

9             You will learn that it was about the money. It was  
10    about saving money on drugs and increasing his profit,  
11    increasing his own bottom line. You will learn that Jessica  
12    Young and Velma Yep hid the drugs when they brought them into  
13    the country because they knew it was wrong. You will learn  
14    that his other employees reported him to the police because  
15    they knew that what was going on was wrong.

16            And at the end of the case the Government will ask  
17    you to determine that the defendant also knew that this was  
18    wrong and return verdicts of guilty on all counts.

19            THE COURT: Thank you.

20            MR. BEHNKE: Thank you, Your Honor.

21            THE COURT: Mr. Gluck, you may proceed. I think we  
22    should go ahead now and take our break after.

23            MR. GLUCK: Either way is fine.

24            Good afternoon, ladies and gentlemen. I've already  
25    introduced myself but, once again, my name is Benjamin Gluck.

1 With me is Jean Rhee and Mark Phillips. We represent  
2 Dr. Patwardhan. We are a little hidden behind here, so it's  
3 good to be able to see you.

4 This case comes down to one thing. It comes down  
5 to the question of whether Dr. Patwardhan knew that there was  
6 a problem with bringing these medicines into the country. We  
7 don't disagree -- as I said earlier, we don't disagree with  
8 the vast majority of the basic facts in this case.

9 Dr. Patwardhan does not deny that he brought  
10 medicine into this country. He didn't deny it the very first  
11 time he was asked about it when Mr. Behnke was just  
12 describing when the agents came to his office. But the issue  
13 is whether he acted with the intent to defraud or deceive  
14 anyone.

15 Now, why does it come down to intent to defraud or  
16 deceive? Because as the Indictment has been read, the  
17 charges that Dr. Patwardhan is charged with, he is charged  
18 with fooling or attempting to fool, to defraud, the Customs  
19 Service, the FDA. He is charged with stealing or engaging in  
20 a conspiracy to steal. He's charged with engaging in a  
21 conspiracy to defraud the United States. And if a person  
22 thinks that what he's doing is legal, if a person thinks what  
23 he is doing is perfectly allowed under the law, then that  
24 shows that there was no intent to fool anyone about it. I'm  
25 going to talk a lot about what the facts show in connection

1 with Dr. Patwardhan's lack of intent to defraud, but let me  
2 tell you first a little bit about his background.

3 Dr. Patwardhan was born in India. He went to high  
4 school, college, and medical school in India. He worked very  
5 hard. He was admitted to a selected medical school there and  
6 he did well. After medical school he came to the United  
7 States to continue his training. He came to this country on  
8 January 1st, 1970, about 40 years ago. At that time and  
9 still today this country offers the best medical training in  
10 the world and he came here to do that.

11 After medical school doctors go through several  
12 years of additional training, internship, residencies, which  
13 are essentially working as a doctor while under supervision  
14 from other doctors, and Dr. Patwardhan did that for several  
15 years when he came to this country. He did that in Virginia;  
16 in Alberta, Canada; in Rhode Island; and in New York.

17 Incidentally, there's no evidence that as part of  
18 this training Dr. Patwardhan was ever trained on FDA approval  
19 processes or labeling regulations.

20 Dr. Patwardhan opened his office in Upland, a  
21 private practice medical office in Upland, just up the road  
22 from here, in September 1976, about 33 years ago. And since  
23 that time he has specialized -- he has had a practice in  
24 Upland for 33 years. He specialized in internal medicine and  
25 oncology. Internal medicine is the treatment of serious

1 diseases not by way of surgery. Oncology is the treatment of  
2 tumors and cancer.

3 Throughout the past 33 years Dr. Patwardhan has  
4 kept up with his medical education, gone to conferences,  
5 seminars, read journals, and done much more training or  
6 professional education than is required by the State, well  
7 above and beyond the State requirements.

8 You will also hear evidence that Dr. Patwardhan was  
9 extraordinarily and still is extraordinarily devoted to his  
10 patients. Many patients were effectively treated for free.  
11 Insurance companies would refuse to pay for another round of  
12 chemo, Dr. Patwardhan's office would provide the chemo, and  
13 if the insurance company didn't pay, the office would absorb  
14 the loss.

15 You will see many aspects of his practice were,  
16 frankly, expensive. He was well staffed. His staff was well  
17 paid. He didn't cut corners on these things because he  
18 wanted to provide high quality patient care. He was devoted  
19 to his patients and his patients were devoted to him. You  
20 will see some of them during the trial. That's  
21 Dr. Patwardhan's background, what he's been doing for the  
22 last 40 years.

23 Let's turn to the facts of this case. As I  
24 mentioned before, this case comes down to one thing. The way  
25 this case is charged, what the Government is accusing

1 Dr. Patwardhan of is fraud. It comes down to whether he knew  
2 there was a problem with bringing in the medicine. And the  
3 first thing that you need to know about this is, the evidence  
4 will show, that Dr. Patwardhan acted -- Dr. Patwardhan  
5 believed that he was permitted to bring that medicine into  
6 this country, and his actions throughout this entire case,  
7 right up to the very day the agents came into his office, are  
8 consistent with a person who believes that what he is doing  
9 is allowed.

10 The evidence in this case is going to show  
11 three things: First, Dr. Patwardhan believed that he was  
12 allowed to bring the medicine into the country. He acted  
13 with the belief that it was legal.

14 Second, Dr. Patwardhan's actions speak to this  
15 issue. If we look at the way he acted, the evidence will  
16 show that for years he acted as a person who believes that  
17 these medicines are legal. He is allowed to have them here.  
18 He is allowed to use them.

19 And the last point the evidence shows is, there is  
20 no allegation that in this case the medicines were dangerous  
21 or didn't work. That's not what this case is about. This  
22 case is about, as the Government has pointed out, it's about  
23 the labeling on the medicine. It's not about the medicine  
24 itself.

25 Now, another very important piece of background



1 before I get to the specific facts here. The evidence will  
2 show that an important factor in this case is a Food and Drug  
3 Administration policy that permits the importation of  
4 medications from other countries carried by travelers into  
5 this country even when those medications are unapproved by  
6 the FDA, and even when their labels don't meet the FDA  
7 requirements. Passengers arrive in this country every day  
8 carrying medication that violates the law. It doesn't meet  
9 the FDA requirements. And the FDA has a policy that says  
10 that they are permitted to bring it in even though,  
11 technically, it violates the law.

12 For many years the FDA has had this policy long  
13 before the events at issue, but it still has it today. It's  
14 called the FDA's Personal Importation Policy. And the FDA  
15 policy says -- and you'll hear a lot about the policy. But  
16 the FDA policy says that Customs agents, the U.S. Customs  
17 agents who are standing at the airport and going through your  
18 baggage and making sure that people bringing things in, have  
19 discretion to allow travelers to bring medication into this  
20 country that does not comply with the FDA approval or  
21 labeling requirements.

22 And this policy you will see has a number of  
23 factors, how much is it, what it's used for, what paperwork  
24 the person is carrying, do they have a prescription,  
25 et cetera, et cetera. Is it some kind of drug that is

1 illegal in the United States, for example.

2 And then the FDA says in its policy, and I quote --  
3 it gives this guidance and then it says in its policy, "The  
4 factors noted in the guidance and the documentation that  
5 should be obtained are not mandatory requirements. They are  
6 intended to guide FDA enforcement discretion and should not  
7 be represented as binding requirements." That's what the FDA  
8 says.

9 In other words, we all know there is a law. The  
10 FDA has regulations requiring approvals and requiring  
11 labeling to be made in a certain way, but the FDA also says  
12 that travelers are allowed to come into this country bringing  
13 medicine that does not comply.

14 And it says, Customs agents, please consider the  
15 following factors. And then it says, but those are not  
16 mandatory. Those are guidance. You should take them into  
17 account. You are allowed to exercise your discretion.

18 One more thing. You will hear from an expert on  
19 this issue, a man by the name of Patrick Egan. Mr. Egan is a  
20 lawyer and he has a lot of experience dealing with this area  
21 of importations of drugs and unapproved labeling and things  
22 like that. He's testified in the United States Congress  
23 about it. And Mr. Egan will testify, he will tell you that  
24 various government agencies have complained that there's a  
25 lot of confusion out there in the public, among the public,

1 about whether it's permitted for a traveler to bring medicine  
2 and under what circumstances is it permitted for a traveler  
3 to bring medicine from a foreign country into the United  
4 States.

5 So that general background out of the way, let's  
6 talk for a moment as to what the evidence is going to show  
7 about what Dr. Patwardhan did. And as I said before, it's  
8 all about whether he knew that these drugs represented a  
9 problem. Did he know it was contraband? Did he try to hide  
10 it from Customs, from Medicare, from anybody?

11 First, Dr. Patwardhan, as I said, comes from  
12 India. Over the years he traveled home quite frequently.  
13 His elderly parents live there. They were ill. They have  
14 since passed away within the last couple of years. He would  
15 travel home whenever he could squeeze in a trip to visit  
16 them, check on their medical care, try to comfort them as a  
17 son would. While he was there he would buy medicine that he  
18 would bring back to use in his practice. There's no dispute  
19 about that.

20 This is a very brief time line of some very  
21 important events in this case. And as I said before,  
22 Dr. Patwardhan's conduct was consistent from the beginning of  
23 this time line until the end.

24 The first -- and I'm going to go through each one  
25 of these in a little more detail, but this time line goes

1 back to April 4th, 2002, which is the beginning of the -- is  
2 before the events described in this Indictment. And that's a  
3 date when Dr. Patwardhan was inspected by Customs. And we'll  
4 talk about that in a moment. And then it goes all the way up  
5 to July 30th, 2008, which is the day that the FDA officers  
6 and other various federal agents came into Dr. Patwardhan's  
7 office in Upland. And you will see in there it also includes  
8 a March 2008 date, which is what Mr. Behnke was talking  
9 about, when one of his employees or more informed the  
10 authorities.

11 First, the evidence is going to show that -- first,  
12 I want to talk about that first date on there, the April 4,  
13 2002 secondary inspection. The evidence is going to show  
14 that on April 4th, 2002, which is just about six months,  
15 maybe just a little over six months after the  
16 September 11th, 2001, terrorist attacks, Dr. Patwardhan  
17 enters Los Angeles International Airport on a flight from  
18 India. He is on Singapore Airlines. He comes into LAX. He  
19 is carrying with him on April 4th, 2002, exactly 280 vials of  
20 medicine that he bought in India. And you will see the  
21 evidence and the documents showing exactly what it was.

22 You will hear and you will see evidence of how  
23 Dr. Patwardhan brought medicine into this country. It was  
24 really very simple. He would carry it in a small bag. For  
25 the trip the medicine would be packed with ice or ice packs,

1 and you'll hear office employees testify that that's how they  
2 received it. And so it would be put in a small duffel bag.

3 In fact, this is the bag or one of the bags. They  
4 were all very similar. And you will hear from the office  
5 staff that this is what they would receive. In fact,  
6 Mr. Behnke has already showed you a picture of the contents  
7 of this bag. You can see right there the picture of the  
8 interior of the bag, the medicine, the vials, in a bag just  
9 like this. He brings this in about six months after  
10 September 11th. He is traveling from India on Singapore  
11 Airlines. He is traveling on an expensive ticket. It's an  
12 expensive flight. He is traveling alone. He bought the  
13 ticket in India instead of in the United States because it's  
14 cheaper that way.

15 You will see later that Customs has -- the Customs  
16 records designate India for inspection purposes as a, quote,  
17 terrorist-affiliated country, subject to higher scrutiny and,  
18 like I said, this is six months after 9/11. He brings this  
19 bag with 280 vials of medicine inside. What does the  
20 medicine look like inside? We know because this is a picture  
21 taken by the Government witness in March of 2008 when he made  
22 a similar trip. Open the zipper and there it is. It's  
23 wrapped in plastic. It's no secret what's in it. There's  
24 ice packs in these pockets at the end to keep it cold.

25 Well, as I said, he comes through with these

1 factors, India, expensive ticket, traveling alone. It was a  
2 very short trip. He had only been in India for a short time.  
3 And Customs refers him for what they call a secondary  
4 inspection. Now, it's a little hard to see this. I'll try  
5 zooming in on some of it. But the first thing you see here  
6 is the inspection date, April 4th, 2002. Dr. Patwardhan  
7 enters the country. And these are Customs records from the  
8 United States Customs Service. He enters the country. He is  
9 referred for a secondary inspection. That means, as you  
10 heard from Mr. Behnke, he is sent for a baggage exam. It  
11 says it right on the document. Sent for baggage exam. Yes.

12 So, Dr. Patwardhan gets sent for the baggage exam,  
13 and the Customs officers complete the baggage exam, complete.  
14 Inspection complete, inspection status complete, secondary  
15 inspection complete. They indicated in the records  
16 three times that they've completed his baggage exam. And  
17 they allow him through with no violations. He's carrying  
18 this bag with 280 vials of medicine with ice packs that look  
19 like this six months after 9/11, and they allow him through.

20 The Customs agents exercised the discretion that  
21 was given to them by the FDA, which you will hear about, and  
22 allowed a traveler to bring medicine into the country. And  
23 even if it didn't quite meet all of the factors that the FDA  
24 sets out, the FDA has given them discretion to decide what to  
25 allow in and what not. That's one time it happened.

1           That's not the only time it happened. The next  
2           date on here is September 8th, 2002. Dr. Patwardhan enters  
3           the country again. This is three days before the very first  
4           anniversary of 9/11. He comes into the country from India on  
5           Singapore Airlines, traveling alone, short trip, expensive  
6           ticket, carrying the duffel bag. This time he's carrying  
7           exactly 400 vials of cancer medicine that was manufactured in  
8           India.

9           Once again, he is referred for a secondary  
10          inspection. He's got this bag, ice packs, vials wrapped in  
11          plastic, another ice pack. Customs sends him over for a  
12          secondary inspection. The date on here, September 8th, 2002,  
13          three days before the first anniversary of 9/11. And they  
14          are inspecting a traveler coming into the country. What do  
15          they do? They do a baggage exam. Yes, they do a baggage  
16          exam. And what do they determine? Inspection complete,  
17          inspection complete, inspection complete, no violations.  
18          Dr. Patwardhan is allowed through. They don't confiscate  
19          anything. They don't cite him. They don't fine him. They  
20          don't take away anything. They allow him through with this  
21          bag with 400 vials of foreign purchased medicine.

22          Now, Mr. Behnke has talked about this inspection on  
23          April 3rd, 2005. On April 3rd, 2005, Dr. Patwardhan came  
24          into the country. Same story. He's referred for a secondary  
25          inspection. This time the reason for the referral is given

1 as, he is traveling from a terrorist-affiliated country. He  
2 is subject to a bag exam. The inspection is completed.  
3 There are no violations.

4 The Customs records show that Dr. Patwardhan was  
5 inspected at least three times, that each time he was  
6 inspected he was permitted through. And the records also  
7 show what he was carrying each time. The first time 280  
8 vials of medicine, and you'll see the records showing what he  
9 was carrying. The second time 400 vials of medicine, and  
10 you'll see the records showing what he was carrying. And the  
11 third time, again, 400 vials of medicine, and you'll see the  
12 records of what he was carrying at that time.

13 Now, Mr. Behnke has said that Agent Cuevas will  
14 testify that he doesn't remember what happened in 2005. This  
15 is the Customs agent whose name is on that record somewhere.  
16 It indicates who the agent was. He is the agent for 2005,  
17 and he says he doesn't remember anything. But Mr. Behnke  
18 says that he will testify that under his practice or his  
19 standards he would have stopped this.

20 The evidence will also show, ladies and gentlemen,  
21 that Agent Cuevas was never asked about this inspection in  
22 2005 until long after Dr. Patwardhan was charged with this  
23 crime. The evidence will show that some people came to Agent  
24 Cuevas and said, we've charged someone with having illegal  
25 drugs in this country and, apparently, they got through on



1 your watch. And the evidence will show that Agent Cuevas  
2 said, "Well, if I would have seen them, I would have stopped  
3 them."

4 Now, Dr. Patwardhan brought the medicine into the  
5 country -- oh, I'm sorry, one more thing.

6 Mr. Behnke mentioned the declarations. The truth  
7 is, the evidence will show that the right way to refer to  
8 that is the lack of declarations, not because something  
9 wasn't declared, but because the Customs Service has thrown  
10 away all of the declarations from all of the trips in which  
11 Dr. Patwardhan is alleged to have carried medicine from  
12 India. They don't keep them very long. They are papers and  
13 they throw them away. And they've thrown them all away in  
14 this case, so we don't have them.

15 The only declaration that the Customs Service has  
16 with respect to Dr. Patwardhan is a trip that he took to  
17 London in the spring of 2008. Now, there's no allegation  
18 that he bought medicine in London or was carrying medicine  
19 when he came back from London. But what's interesting about  
20 that declaration is that you'll see that in that declaration  
21 Dr. Patwardhan declared a \$20 silver souvenir cup that he had  
22 brought back from London. So the only declaration that we  
23 have shows that he certainly did declare.

24 Second, when the Customs officer is inspecting  
25 Dr. Patwardhan, when he's doing that secondary inspection

1     that we've seen all those records of, he's got the  
2     declaration. So if he looks in the bag and sees 280 vials,  
3     400 vials, he knows what the person is carrying. Whatever  
4     was on that declaration satisfied the Customs officer. That  
5     much we do know, because there's no indication that he was  
6     cited for a failure to declare. So, as far as the  
7     declarations go, all we know is they're missing because  
8     Customs threw them away, but the one we have shows he did  
9     declare. And the ones that are missing, he certainly wasn't  
10    cited for failing to declare, even though his baggage was  
11    inspected.

12               Now, that's the way the medicine came into the  
13    country. It happened many, many times. We don't have  
14    Customs records showing that he was inspected every time, but  
15    you will see Customs records, like I've shown you, showing  
16    that he was inspected at least several times. And, I'm  
17    sorry, when I say "inspected," there's a secondary baggage  
18    exam.

19               But Dr. Patwardhan's actions long after he left the  
20    airport also show that he acted consistent with a person who  
21    has just been allowed, through the exercise of the Customs  
22    officer's discretion, to bring the medicine into this  
23    country.

24               What happened when he came into the country? What  
25    does he do with the medicine? Now, this is what the medicine

1 looks like. And this is a picture of one of -- or some of  
2 the vials of medicine. And it says right here, "Manufactured  
3 in India by Dr. Reddy's Laboratories Biotech Division." This  
4 one says in Spanish that it's -- it's in Spanish. It's made  
5 in Italy and it is by some Italian company. Anybody looking  
6 at this medicine can see right away where it comes from.  
7 It's no secret.

8           So, does he bring it back to his office and put it  
9 in his safe? The evidence is going to show that he didn't do  
10 that. He didn't put it in a safe. He didn't put it in a  
11 closet. He didn't put it in a secret hiding place. No, he  
12 gave it to his employees, the employees in his office whose  
13 job it was to handle the medicine, meaning they would order  
14 medicine from the other companies, they would receive it,  
15 they would unpack it, they would inspect it, they would put  
16 it on the shelf. He took this medicine in this bag. He  
17 didn't bother to unpack it. He didn't bother to pretty it  
18 up. The evidence -- I showed the picture before of what it  
19 looks like, and he handed that to the employees and said,  
20 "Here, please process this." And they did.

21           Part of their job was to check the medicine against  
22 the inventory. I believe Mr. Behnke mentioned that. The  
23 inventory -- I'm sorry, check the medicine against the  
24 invoice. The invoice, which you will see many of them, the  
25 invoice says, right on the invoice, that it was bought in

1 India. The invoices Jessica Young would provide say right on  
2 there that they were bought in Honduras. It was not a secret  
3 from anyone and there was no effort to keep it a secret from  
4 anyone. The office staff checked off the invoice and signed  
5 it just like they would do as part of their job with any  
6 other medicine. And then they would send -- and you'll see  
7 the staff signatures on the invoices. And they would send  
8 those invoices over to the business side of the office.

9           Where did they put the medicine? The medicine was  
10 stored in an open and accessible area. Like I said before,  
11 not in a safe, not in a locked closet, not in a locked  
12 drawer. It was kept on a shelf or in the refrigerator, some  
13 of it needs to be refrigerated, some of it doesn't, along  
14 with all the other medicine in a space in the office which --  
15 this is just to orient things. This is a picture of the  
16 patient treatment room. Mr. Behnke showed a picture of this  
17 room before, but that one was facing the other direction,  
18 facing into the corner. Facing out of this room you can see  
19 that counter which is the border of -- there's a hallway that  
20 goes down that way past that TV which is the center hallway  
21 of the office. Anybody wants to go anywhere in that office  
22 needs to walk down that hallway.

23           If you look right over that counter, you can see  
24 and get a peek. It's more than a peek. It's a brown  
25 cabinet. That's the room that the medicine was kept in.

1 Now, not only was this medicine not kept behind locked doors,  
2 it was in this cabinet. It is in the refrigerator. Not only  
3 was it not kept behind locked doors, there isn't even a door  
4 on this room. Not only is there no lock, there isn't even a  
5 door on this room. Those cabinets are kept unlocked. The  
6 staff is in and out of that room all the time. And it's  
7 stored right there on the shelf.

8 Now, what happens when -- what happens when -- they  
9 unpack the medicine. You've seen what it looked like. They  
10 put it on the shelf.

11 Remember the invoice? Somebody signs off on the  
12 invoice. What happens to the invoice? Well, it goes over to  
13 the business side of the office and it gets paid, just like  
14 other business expenses. Once it gets paid, what happens to  
15 the record of it? Remember, these are records showing that  
16 someone is buying medicine in India, buying medicine in  
17 Honduras. They are evidence of a crime. What happens to  
18 them? They are not shredded. They are not thrown away.  
19 They are not burned or hidden or anything like that. They  
20 are put on a shelf in a file that in big black letters says  
21 "Invoices." They are put in a box that says "Wires." And  
22 those are maintained just like all the other office records  
23 showing the purchase of medicine, showing the payments of  
24 bills.

25 In fact, when the company prepares -- or the

1 practice prepares its taxes every year, they would provide  
2 copies of these invoices to their accountant, if necessary,  
3 to show their expenses. In fact, Jessica Young sent copies  
4 of the checks to Honduras -- in other words, a check going to  
5 pay for Honduran medicine, she sent those to the accountant  
6 so that he could provide them to the Internal Revenue Service  
7 when it audited the practice's taxes. There was no  
8 evidence -- there is no evidence that anybody tried to hide  
9 these invoices from anyone.

10 In fact, when time went on, and generally, as  
11 office records grow and grow and grow, eventually you run out  
12 of room. And so a medical practice over many years, there's  
13 lots of records, not just these invoices, but just all office  
14 records, records get sent to storage. And these invoices and  
15 these wires, this proof of the crime, is sent to storage, and  
16 Dr. Patwardhan paid to keep it. There's no requirement to  
17 keep it for a day, but he never asked anyone to throw it away  
18 or shred it or hide it or anything. He paid to maintain it.  
19 He kept it on the shelf. It was so clearly labeled that when  
20 the FDA came in, they found it right away. There was no  
21 effort to hide anything from anyone.

22 Going back to the medicine, okay? The medicine was  
23 put up on the shelf. We talked about the invoice and how it  
24 was paid and where it was maintained. The medicine is on the  
25 shelf. The manner in which the medicine was used is also

1 consistent with -- and, frankly, only consistent with -- a  
2 person who thinks this is legal, with a person who thinks  
3 that, yes, I brought this into the country because the United  
4 States Customs Service, exercising their discretion, allowed  
5 me to.

6 First --

7 THE COURT: Refrain from argument. Thank you.

8 MR. GLUCK: Sorry, Your Honor.

9 Most of these medicines are administered in the  
10 office. The evidence will show that most of the medicine is  
11 administered in the office, but you will also hear from a  
12 patient Mr. Behnke mentioned who received medicine that had a  
13 label on it, a label on it showing that it was not FDA  
14 approved. No effort to hide that from this patient. She was  
15 given that to take home.

16 Now, you will also hear from other office staff  
17 that the way the medicine was used, they would --  
18 Dr. Patwardhan -- a lot of this medicine was administered  
19 through intravenous drips. It had to be mixed with saline  
20 solution and administered through an IV. So he had to  
21 reconstitute it, make it liquid.

22 They would take out the medicine, put it on the  
23 counter. It would sit on the counter, made in India. It  
24 would sit on the counter until he would reconstitute it.  
25 Then the evidence will show he didn't take those vials and

1 throw them away. He didn't hide them. He didn't destroy  
2 them. No, he left them on the counter. It was the office  
3 staff's job to clean them up. He left them on the counter.  
4 And we've seen, ladies and gentlemen, that space where they  
5 were left is right next to where everyone walks through the  
6 office. The patients sit in those easy chairs that I  
7 displayed before, and they are sitting steps away from where  
8 this medicine is kept or is placed.

9 In fact, one of the office staff will testify that  
10 one of her jobs was to take this medicine off the shelf and  
11 put it on a little table that is literally at the patient's  
12 elbow, literally at the patient's elbow. And she would put  
13 it there and it would be used during the chemotherapy  
14 process.

15 Now, the Government has talked a lot about the  
16 names that were used in the files and that the names referred  
17 to -- he used the example of Taxotere. Taxotere is a U.S.  
18 brand name. Docetax is an Indian brand name. Docetaxel is a  
19 chemical name. You will hear from an expert witness, an  
20 oncologist, who will testify that there are many medicines  
21 that are marketed and sold legally under many different  
22 names. And the practice among doctors is to use the most  
23 common name for the medicine, even if -- or, to use his  
24 example, it's kind of like Kleenex, that I could refer to  
25 Kleenex even though really I mean any type of facial tissue.



1 So the use of the generally known name by which all doctors  
2 always refer to that medicine is consistent with a person who  
3 is not trying to fool anyone.

4 As far as billing is concerned, part of this case  
5 is about billing. And the Government says that  
6 Dr. Patwardhan tried to fool Medicare into paying for  
7 medicines that came from India. But the important thing to  
8 know about the billing, there's two things to know about the  
9 billing. First, Medicare reimburses for all of these types  
10 of cancer medications based on a flat rate. It doesn't  
11 matter how much the doctor paid for it. It's not --

12 THE COURT: Mr. Gluck, first of all, you have about  
13 five minutes left, and refrain from arguing.

14 MR. GLUCK: I'm sorry.

15 THE COURT: Thank you.

16 MR. GLUCK: The evidence will show that Medicare  
17 pays for these medicines on a flat rate. The payment is  
18 keyed to the medicine or the type of medicine given, not how  
19 much the doctor paid for the medicine.

20 The evidence will also show that the way a medical  
21 office reports these expenses to Medicare is by use of a  
22 series of codes. Every one of these medicines has a code.  
23 These codes happen to start with the letter J. They are  
24 known as J codes. You will hear, ladies and gentlemen, that  
25 the J codes that Medicare gives to medicines are not based on

1 brand names. It does not say Taxotere. It says Docetaxel,  
2 the chemical name. And the evidence will show that the  
3 chemical names under which these medicines were billed were  
4 accurate. You will also hear evidence, ladies and gentlemen,  
5 that Medicare didn't pay more to reimburse these medicines  
6 then it would have paid otherwise.

7 Now, let me briefly touch on the March 2008 picture  
8 taking incident that Mr. Behnke mentioned. The thing that's  
9 important to keep in mind is that the evidence shows that  
10 after March of 2008 -- actually, let me go straight to this  
11 one. After March of 2008, the FDA didn't come into  
12 Dr. Patwardhan's office until July 30th, 2008, about  
13 four months later.

14 In the interim, Dr. Patwardhan did not destroy  
15 anything. He didn't hide the medicine. The evidence will  
16 show that he didn't shred the records. The evidence will  
17 show that when the agents came into his office on July 30th  
18 of 2008 and told him they were looking for drugs from India,  
19 they found the drugs where they had always been.

20 When they asked him, "Are you bringing drugs from  
21 India?"

22 He said, "Yes."

23 When they said, "How many times have you done  
24 this?"

25 He said, "Many times."

1           He didn't change -- the evidence will show that he  
2       didn't change his conduct one bit during those four months  
3       when he knew that someone had told the authorities.

4           I've got one more point about the evidence and I'll  
5       stop. You've heard the Government talk about Jessica Young.  
6       And Jessica Young brought medicine from Honduras and she will  
7       testify to that. And she is a Government witness. She is  
8       testifying on behalf of the Government. Ms. Young has met  
9       with the Government many times and has testified under oath  
10      in the Grand Jury and promised to tell the truth. And  
11      Ms. Young has testified under oath and has told the  
12      Government in interviews that every time she brought medicine  
13      from Honduras -- and the evidence will show that she brought  
14      more medicine than Dr. Patwardhan did -- every time she did  
15      it, she did it with the belief that it was legal.

16           And, as far as the declarations are concerned, she  
17      will testify, and she has already, that Dr. Patwardhan told  
18      her that she needs to pay duty on the medicine.

19           Ladies and gentlemen, this case is about whether  
20      Dr. Patwardhan acted with intent to defraud, whether he acted  
21      like someone who thinks that what he's doing is allowed or he  
22      acted like someone who is trying to hide something from  
23      someone. From the beginning of that time line all the way to  
24      the end, from the times he was inspected at the airport  
25      carrying this bag, all the way to the day the authorities sat

1 down with him and said, are you bringing drugs from India,  
2 Dr. Patwardhan has acted consistent with a person who  
3 believes that he is allowed to have this medicine here  
4 because the Customs agents allowed him to bring this medicine  
5 here, consistent with the FDA's discretionary policy.

6 When the case is over, we will ask that you find  
7 Dr. Patwardhan not guilty on all counts.

8 THE COURT: Thank you.

9 All right. Ladies and gentlemen, we'll take our  
10 afternoon recess. We will be in recess for 15 minutes which  
11 would make it about 3:40 by the courtroom clock. Remember  
12 what I've admonished you before or instructed you. Do not  
13 discuss the case with anyone, amongst yourselves, or with  
14 anyone else, anything related to the case in the broadest  
15 possible sense, anything you've heard in the courtroom, seen  
16 in the courtroom, any of the participants, attorneys  
17 witnesses. We haven't heard from witnesses yet. You haven't  
18 heard any evidence yet, only the statements of the lawyers  
19 which is not evidence. Don't do any investigation about the  
20 case. Don't do any research about the case in any fashion.  
21 Don't make up your minds about the case or anything having to  
22 do with the case.

23 Thank you, ladies and gentlemen. We are in recess.

24 (Recess)

25 THE COURT: Let the record reflect the presence of

1 all members of the jury, all counsel, and the defendant also  
2 present.

3 The Government may call its first witness.

4 MR. WIDMAN: Thank you, Your Honor. The United  
5 States calls Norma Franco.

6 THE COURT: Thank you.

7 PLAINTIFF'S WITNESS, NORMA FRANCO, WAS SWORN

8 THE CLERK: Please be seated. Please state your  
9 full name and spell it for the record.

10 THE WITNESS: Norma Franco, N-O-R-M-A,  
11 F-R-A-N-C-O.

12 THE COURT: Ms. Franco, very carefully adjust that  
13 microphone. It's a little fragile, that's why I say  
14 carefully. There you go.

15 There's a pitcher of water and some cups right  
16 there behind that monitor. Help yourself if you want some  
17 water.

18 THE WITNESS: Thank you.

19 THE COURT: Keep your voice up. I'll let you know  
20 if you need to speak louder. Wait until the attorney has  
21 finished his question before you begin your answer, all  
22 right? Thank you.

23 You may inquire.

24 MR. WIDMAN: Thank you, Your Honor.

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1 Q. What was your role?

2 A. I was a medical assistant and I worked there for  
3 eight years. I would check in patients, take vital signs,  
4 blood draw. I would order medications, stock the rooms,  
5 clean up the chemo area.

6 Q. What month and year, approximately, did you begin  
7 working in Dr. Patwardhan's office?

8 A. August of 2000.

9 Q. And when did you end your employment?

10 A. July 23rd of 2008.

11 Q. Okay. At this point I would like you to pull out the  
12 first of those three binders that are to your right and just  
13 behind you. And I would like you to look at the pictures  
14 that are behind the tabs 1 through 1W and just look them over  
15 to yourself.

16 A. Okay.

17 Q. Do those pictures fairly and accurately depict  
18 Dr. Patwardhan's medical offices at 918 West Foothill  
19 Boulevard in Upland, California?

20 A. Yes.

21 MR. WIDMAN: Your Honor, the Government moves to  
22 have Exhibits 1 through 1W entered into evidence and  
23 published for the jury.

24 MR. GLUCK: No objection.

25 THE COURT: Thank you. Exhibit 1 is ordered

1 admitted and you may publish.

2 MR. WIDMAN: Your Honor, the way that we organized  
3 the exhibit books is that there's 1, 1A, 1B, and all of the  
4 exhibits that have the same number sort of have the same  
5 similarity. In this case they're all from the same office.  
6 So the Government is requesting that 1 through 1W, each of  
7 those be entered into evidence.

8 THE COURT: Well, isn't -- I'm sorry, maybe I  
9 misunderstood. There is no other subparts of Exhibit 1, is  
10 there, than 1 through W?

11 MR. WIDMAN: That's correct.

12 THE COURT: A through W, I should say.

13 MR. WIDMAN: That's correct.

14 THE COURT: So all of it is ordered admitted.

15 MR. WIDMAN: Very well, Your Honor.

16 THE COURT: And you may publish whatever parts of  
17 it you wish.

18 MR. WIDMAN: Thank you, Your Honor.

19 THE COURT: You're welcome.

20 BY MR. WIDMAN:

21 Q. Ms. Franco, could you please turn to Exhibit 1. And  
22 just for clarity sake, it starts with 1, the next is 1A and  
23 so forth. What is this is that you see in Exhibit 1?

24 A. This is the front office, the front door.

25 Q. Okay. This is Dr. Patwardhan's office; is that right?



1 A. Yes.

2 Q. Please take a look now at Exhibit 1A. What is this,  
3 Ms. Franco?

4 A. This is the front door.

5 Q. Thank you. Exhibit 1B, please, could you tell us what  
6 this is?

7 A. This is the waiting area for the patients.

8 Q. Exhibit 1H, please. And this?

9 A. That's the reception area.

10 Q. So what would happen at this area?

11 A. This is where the receptionists sit.

12 Q. Would patients ever come to this area?

13 A. No.

14 Q. 1K, please. Please take a look at Exhibit 1K. Do you  
15 recognize -- I guess you told us you recognize it.

16 Can you tell us what this is, Ms. Franco?

17 A. This is Room 4. It is the examination room where we do  
18 all the treadmills.

19 Q. When you say you do the treadmill, what do you mean by  
20 that?

21 A. We do stress tests for patients, internal medicine  
22 patients.

23 Q. Please take a look at Exhibit 1L. Could you tell us  
24 what this is?

25 A. This is the lab.

1 THE COURT: Ms. Franco, you need to keep your voice  
2 up a little bit.

3 THE WITNESS: Okay.

4 THE COURT: Thank you.

5 BY MR. WIDMAN:

6 Q. What happened here?

7 A. This is where Dr. Patwardhan mixes chemotherapy. This  
8 is where we have the chemo vials, all injectables,  
9 medications.

10 Q. And is this where you would set up the chemo materials?

11 A. Yes.

12 Q. Exhibit 1U, please. Can you tell us what goes on here?

13 A. This is where we administer the chemotherapy.

14 Q. So where would the patient sit in this picture?

15 A. They would sit in the recliners.

16 Q. And were the cabinet doors ordinarily open like that?

17 A. Yes.

18 Q. Okay. Now that we've seen a few of the pictures, we  
19 talked -- I think you mentioned before that one of your  
20 responsibilities was setting up chemo?

21 A. Yes.

22 Q. What did you mean by that?

23 A. The day before chemo I would set up the lab with the IV  
24 saline bags with the patient's names on the bags and the  
25 milligrams of the medication that the patient was going to be

1 getting with the vials next to those bags, syringes, gloves,  
2 the mask, things that the doctor was going to use to mix the  
3 chemotherapy.

4 Q. And how did you know which drugs to put out for?

5 A. 'Cause we would have the patient's chart and we would  
6 write down the name of the medication, and we would write  
7 that name of the medication on the IV bags.

8 Q. Would you write anything else on the IV bag?

9 A. The last name of the patient, the milligrams, and the  
10 name of the medication.

11 Q. Which room within the medical office did you set up the  
12 chemo?

13 A. In the lab.

14 Q. I would like you to take a look now at Exhibit 1L. You  
15 can actually just look at the screen. Ms. Franco, is your  
16 monitor on?

17 A. No.

18 Q. There probably is a little button where you can turn it  
19 on.

20 A. It's on, just no picture.

21 Q. There's no image there? Okay. I'm going to set this on  
22 here. You mentioned the lab. Is this what you were  
23 referring to?

24 A. Yes.

25 Q. Can you show us by indicating with your finger on the

1 screen where you would set up the chemotherapy?

2 A. This right here is where the doctor would mix the chemo.  
3 And right over here, this area, this is where we would put  
4 the IV bags and the medications and syringes and gloves and  
5 the mask.

6 Q. Where were the materials that would be used to set up  
7 the chemo located?

8 A. In these cabinets up here. The medications would be  
9 right here.

10 Q. And were there any medications in the refrigerator?

11 A. Yes.

12 Q. And I believe you can tap the lower right-hand corner of  
13 the screen to clear it or the lower left-hand.

14 THE COURT: Right-hand.

15 MR. WIDMAN: Is it the right-hand corner?

16 BY MR. WIDMAN:

17 Q. See if that works.

18 I now would like you to take a look at Exhibit 1Q.  
19 Could you tell us what is located in these cabinets, if  
20 anything?

21 A. In these cabinets here there is just prescription  
22 medication. On this one here is where the chemo medication  
23 vials are stocked.

24 MR. WIDMAN: Okay. And for the record, Ms. Franco  
25 is referring to the cabinet to the furthest left part of the

1 image.

2 BY MR. WIDMAN:

3 Q. Is that right, Ms. Franco?

4 A. Yes, this one right here.

5 Q. In the foreground, if you will. Turning now to  
6 Exhibit 1R, please, in relation to the cabinets that we were  
7 just looking at, where are these cabinets? You might want to  
8 clear the screen, please.

9 My question was, where are these cabinets in  
10 relation to the ones we were just looking at?

11 A. Those are located on the right-hand side of the lab.

12 Q. And what are contained in these cabinets?

13 A. Medications, samples of just regular medication, drugs.

14 Q. Let's take a look at Exhibit 1M.

15 Actually, you know, I just want to ask one other  
16 question regarding 1R. Towards the bottom part of the screen  
17 there appears to be something that says "Chemo meds" where my  
18 finger is pointing. Do you recognize that?

19 A. Yes.

20 Q. What is that?

21 A. That's a log where we write down the medications that we  
22 order from the distributor.

23 Q. And what are located in the cabinets right to the left  
24 of that?

25 A. There we have like needles to draw blood.

1 Q. Thank you. Now, turning to Exhibit 1M, what is depicted  
2 in this picture?

3 A. These are refrigerated medications that are used for  
4 chemotherapy.

5 Q. And what do you see on the middle shelf, if you will,  
6 right above where it says -- it has that neon sign that says  
7 "Prime Care Patients Individual Meds." What do you see  
8 there?

9 A. Taxotere.

10 Q. Okay. So there's a bin there that has handwritten on it  
11 "Taxotere"?

12 A. Yes.

13 Q. And what is below that?

14 A. Procrit.

15 Q. And again, is that a prewritten label or is it  
16 handwritten?

17 A. It's handwritten.

18 Q. And these are drugs that are used in the treatment of  
19 cancer?

20 A. Yes.

21 Q. I now would like to show you Exhibit 1N. Could you tell  
22 us what's in this picture?

23 A. This is on the door of the refrigerator. There's also  
24 some medications that are used for chemo and there's insulin  
25 also.

1 Q. And now 1P. And what is in this picture, Ms. Franco?

2 A. Neumega. That's also used for chemotherapy.

3 Q. And is that in the inside of the refrigerator or outside?

4 A. It's inside the refrigerator on the door.

5 Q. Let's take a look now at Exhibit 1S. What do you see  
6 here, Ms. Franco?

7 A. This is the cabinet where all the chemotherapy vials are  
8 kept in.

9 Q. Okay. Is there any indication on the shelves themselves  
10 what drugs are there?

11 A. Yes.

12 MR. WIDMAN: For the record, I'm going to zoom in.

13 BY MR. WIDMAN:

14 Q. Could you please point out where in the picture there is  
15 such indications?

16 A. (The witness complies).

17 Q. Thank you. And finally, 1T. What is in this picture,  
18 Ms. Franco?

19 A. This is our lower cabinets. This is where we keep the  
20 IV saline bags and also saline water that is used to mix the  
21 chemotherapy and also chemotherapy vials.

22 Q. Can you point out for the jury where the IV bags are?  
23 You may want to clear the screen. Thank you.

24 A. (The witness complies).

25 MR. WIDMAN: And for the record, Ms. Franco has

1 indicated the upper right quadrant of the shelves.

2 BY MR. WIDMAN:

3 Q. Who had the final say on which drugs were administered  
4 to particular patients?

5 A. Dr. Patwardhan.

6 Q. And I think we may have mentioned this before, but how  
7 did you know which drugs to put out for the doctor?

8 A. We would look in the patient's file and we would see the  
9 medications that were given the week or two weeks before,  
10 depending on how their chemo is given.

11 Q. And then after you set up the chemotherapy treatments,  
12 what would happen next to the treatments?

13 A. Can you repeat that?

14 Q. Sure. After you set up the treatments, what happened  
15 next to the treatments? Did anyone mix them at any time?

16 A. After I would set up the chemo, Dr. Patwardhan, the  
17 following morning at 7:00, he would come in and mix the  
18 chemo.

19 Q. What do you mean by mix the chemo?

20 A. He would mix the chemotherapy vials with saline water  
21 and mix the milligrams that the patient is supposed to be  
22 getting and mix it into the IV bag.

23 Q. Did you ever personally see him mixing the chemotherapy  
24 treatments?

25 A. Yes.



1 Q. And did you play any part in -- well, let me ask you  
2 this: After he was done mixing the chemotherapy treatments,  
3 what happened next on the counter?

4 A. We would get all the bags together for that particular  
5 patient, put them all together. And once the patient came  
6 in, we would do the vital signs and then put all the bags  
7 where that patient was going to be seated and then the IV  
8 would be started.

9 Q. After Dr. Patwardhan finished mixing the chemo, was  
10 there anything left over on the counter?

11 A. Yes.

12 Q. What was left over on the counter?

13 A. The vials that were used to mix the chemo.

14 Q. And did you play any part in clearing that off?

15 A. Yes. We would clean the counters after all the patients  
16 were gone and dispose of them.

17 Q. I believe you mentioned before, did you play any role in  
18 billing?

19 A. We would do the charge slips for the patients that  
20 received the chemotherapy, and we would give them to the  
21 billing department.

22 Q. What is a charge slip?

23 A. A charge slip is where the names of all the drugs are on  
24 there with milligrams and there's like billing codes on them.  
25 And we would check off the medication that was given to the

1 patient.

2 Q. Was there any other forms that were used that you  
3 prepared in connection with billing of the patients?

4 A. There was a progress note. That's where we would write  
5 down the patient's name, their vital signs and the chemo  
6 medications that the patient was going to be getting with the  
7 times the medications were administered. And then we would  
8 make a copy of that and attach it to the charge slip, and  
9 then it would go to the billing department.

10 Q. When would you fill out the progress note and the charge  
11 slip?

12 A. We would do it the day before chemotherapy.

13 Q. I would like to show you -- how about this: Could you  
14 please look in the binder at Exhibits 112 through 112D. And  
15 just look them over for yourself. Oh, yes, Ms. Franco, it's  
16 in binder No. 3. There's three binders. Exhibit 112 through  
17 112D, please.

18 A. You said binder No. 3?

19 Q. Yeah. It should start with -- Exhibit 112 should be in  
20 there. That's how you know you have the right binder. So  
21 please look over 112 through 112D. Could you tell us what  
22 you see there?

23 A. It's the charge slip. This is where we would write the  
24 patient's name, the diagnosis of the patient, the co-payment  
25 that the patient had to pay, and we would check off all the

1 medications that were administered that day.

2 Q. And do these exhibits -- are they the same forms that  
3 you used when you worked in Dr. Patwardhan's office?

4 A. Yes.

5 MR. WIDMAN: Your Honor, the Government moves to  
6 have Exhibit 112 through 112D or Exhibit 112 --

7 THE COURT: A through D, is that it?

8 MR. WIDMAN: Exactly, 112A, B, C and D moved into  
9 evidence and permission to publish.

10 THE COURT: Any objection?

11 MR. GLUCK: No objection, Your Honor.

12 THE COURT: Thank you. 112A through D is ordered  
13 admitted and you may publish.

14 MR. WIDMAN: Thank you, Your Honor.

15 BY MR. WIDMAN:

16 Q. I am now putting on the overhead projector, and you may  
17 want to clear the screen, Exhibit 112. Let's take a look at  
18 this. Could you please explain to the jury, sort of walk  
19 through what this all means in this exhibit.

20 A. This is the date. And this is where we write the  
21 diagnosis. This is the co-payment that the patient has to  
22 pay if they have a co-payment. And these check marks are the  
23 medications that we check off. And this is the milligrams  
24 that the patient received.

25 Q. Okay. Right here where it says "Name," what would

1 ordinarily be written there?

2 A. The patient's name.

3 Q. Now, could you please clear the screen, Ms. Franco?

4 A. Yes.

5 Q. Thank you.

6 So if you were to administer a particular drug,  
7 let's say, for example, you were to administer Taxotere, how  
8 would you indicate that on this form?

9 A. We would check mark this one here and write the  
10 milligrams here.

11 Q. And what if the drug you were administering wasn't on  
12 the form?

13 A. We would write it in this area, wherever there is an  
14 empty space.

15 MR. WIDMAN: And for the record, Ms. Franco is  
16 pointing to sort of the center column which is blank on the  
17 page.

18 BY MR. WIDMAN:

19 Q. Now, I'd like you to take a look at Exhibit 113 to 113D.  
20 And just review them for yourself and then I'm going to ask  
21 you some questions about them. What are those exhibits?

22 A. This is the charge slip. This is where we write down  
23 the patient's weight, the CBC that is done that morning, the  
24 name of the medications that the patient is getting, and the  
25 diagnosis.

1 Q. Do you see your handwriting anywhere on Exhibit 113?

2 A. Yes.

3 Q. Is yours the only handwriting on the page?

4 A. No. The top portion is Mayra Jaurequi.

5 Q. Are these forms the same kind of forms you used during  
6 your time as a medical assistant in Dr. Patwardhan's office?

7 A. Yes.

8 MR. WIDMAN: Your Honor, the Government moves to  
9 have Exhibits 113, 113A through D moved into evidence and  
10 permission to publish.

11 THE COURT: Any objection?

12 MR. GLUCK: No objection.

13 THE COURT: Thank you. 113 and 113A through D are  
14 ordered admitted and you may publish.

15 MR. WIDMAN: Thank you, Your Honor.

16 BY MR. WIDMAN:

17 Q. I'm putting Exhibit 113 on the overhead projector. And  
18 just like you did with the other document we were looking at,  
19 can you please walk us through what you see here.

20 A. This is where we would write the patient's name. This  
21 top corner right here is the initials of the nurse, the  
22 medical assistant that brought in the patient that morning.

23 Q. And whose initials are these, if you can tell?

24 A. These are my initials.

25 Q. Thank you. Please continue.

1 A. The date. And this is the CBC that was done in the  
2 morning.

3 Q. What does CBC mean?

4 A. CBC is to check your white blood count, your red blood  
5 cells and your platelets just to make sure that -- if your  
6 white blood cells are too low, the doctor normally doesn't  
7 give chemotherapy, so he will postpone it for the following  
8 week.

9 Q. And would someone sign off on this form once it was  
10 completed to authorize it?

11 A. Yes.

12 Q. Can you please indicate for the jury where they would  
13 sign?

14 A. Right here at the lower part of the form.

15 Q. And, typically, who in the office would sign?

16 A. Dr. Patwardhan or the nurse practitioner.

17 Q. And who is the nurse practitioner?

18 A. Velma Yep.

19 Q. Thank you. Are you familiar with the expression "no  
20 charge"?

21 A. Yes.

22 Q. What does it mean?

23 A. Where there's no charge when the patient is seen, they  
24 don't pay anything.

25 Q. And who would decide whether a patient should be no

1 charged?

2 A. Dr. Patwardhan.

3 Q. How often would Dr. Patwardhan no charge for  
4 chemotherapy medications?

5 A. Never.

6 MR. GLUCK: Objection, Your Honor, speculation.

7 THE COURT: Overruled.

8 BY MR. WIDMAN:

9 Q. Let me ask you this: Were there ever times where you  
10 witnessed Dr. Patwardhan no charge for any kind of patient?

11 A. Yes.

12 Q. Did you ever see him do that for chemotherapy patients?

13 A. No.

14 Q. Changing subjects now, did you learn at some point that  
15 Dr. Patwardhan was bringing drugs into the United States from  
16 India?

17 A. Yes.

18 Q. When did you first notice that?

19 A. When I first started working in the Upland office.

20 Q. And what year was that?

21 A. I believe it was in 2003.

22 Q. How many trips -- how often would he make the trips?

23 A. He would go about three, four times a year.

24 Q. And how would he bring the drugs back?

25 A. In a gym bag, a Reebok gym bag.

1 Q. And could you describe what the drugs -- well, first of  
2 all, did you ever have an opportunity to look inside of those  
3 bags?

4 A. Yes.

5 Q. Could you describe what you saw when you looked inside?

6 A. There was chemotherapy drugs inside of the gym bag and  
7 on the side of the duffel bag.

8 Q. Was there any packaging?

9 A. Yes. They were packaged in clear tape. They were all  
10 like -- they weren't bubble wrap. Some of them were bubble  
11 wrap and some of them were wrapped in like Scotch tape.

12 Q. Was there any written or printed materials in there like  
13 instructions or anything along those lines?

14 A. No.

15 Q. Would the drugs be refrigerated?

16 A. Some of the bags did come with ice packs on the side of  
17 the gym bag.

18 Q. And when you saw the bags, what temperature were the ice  
19 packs at?

20 A. At room temperature.

21 Q. And the drugs themselves, what temperature would they  
22 be?

23 A. Room temperature.

24 Q. Were these drugs that were ordinarily refrigerated?

25 A. Yes, some of them.



1 Q. Did Dr. Patwardhan ever use dry ice to keep the vials  
2 cold?

3 A. No.

4 Q. I'm sorry?

5 A. No.

6 Q. And how many vials would be in the bag?

7 A. Maybe about 200.

8 Q. And for how long would that supply the medical practice,  
9 typically?

10 A. Last about three months.

11 Q. Did you ever see him mixing drugs that he had brought in  
12 from India into the bags -- excuse me. Strike that, please.

13 We talked before about witnessing him mix  
14 chemotherapy medications. Do you remember that?

15 A. Yes.

16 Q. Did you ever see him mixing drugs brought into the  
17 office from India in that way?

18 A. Yes.

19 Q. Okay. Let's step back. Once the drugs were brought  
20 into the office, how would you first encounter them?

21 A. He would leave them on the lab counter or he would -- if  
22 I was doing something, he would call my name or call another  
23 medical assistant to count the vials.

24 Q. And when you say "count the vials," what do you mean?

25 A. We would have to count the vials to make sure that the

1 right amount was in there for what he paid for it.

2 Q. And what would you do when you were done doing that?

3 What would you do with the drugs?

4 A. We would put them away in the cabinets.

5 Q. Did you keep any kind of record reflecting what you were  
6 doing?

7 A. Yes.

8 Q. What would you call that? What would you call that?

9 A. We would write it normally on lined paper and write the  
10 names of the drugs and how many were counted for, and we  
11 would write our initials and date it.

12 Q. Who would ask you to count out the drugs?

13 A. Dr. Patwardhan and Jessica Young.

14 Q. Who is Jessica Young?

15 A. She is the office administrator.

16 Q. Thank you. I'd like you to look in your exhibit binder  
17 there at Exhibit 114 through 114B. Could you tell us what  
18 you see there?

19 A. This is the paper where we would write the name of the  
20 medication and the number of vials that we counted for with  
21 our initials. And they were given to the administrator.

22 Q. And each of these three exhibits, are they in your  
23 handwriting?

24 A. Yes.

25 Q. And are your initials on each of them?

1 A. Yes.

2 MR. WIDMAN: Your Honor, the Government moves to  
3 have Exhibits 114, 114A and 114B moved into evidence and  
4 permission to publish.

5 THE COURT: Any objection?

6 MR. GLUCK: No objection, Your Honor.

7 THE COURT: Thank you. Exhibits 114, 114A and B  
8 are ordered admitted. You may publish.

9 MR. WIDMAN: Thank you, Your Honor.

10 BY MR. WIDMAN:

11 Q. I'm now putting on the overhead projector Exhibit 114.  
12 Could you please walk the jury through what they see here?

13 A. This is the date. This is my initials. And these are  
14 the names of the chemo medication drugs. And here are the  
15 number of drugs counted for.

16 Q. And here, next to your initials, what is that writing to  
17 the right there?

18 A. MA.

19 Q. What does that mean?

20 A. Medical assistant.

21 Q. Thank you. Could you please clear the screen?

22 A. (The witness complies).

23 Q. Were there ever times when you were counting the drugs  
24 when you weren't sure what kind of drug it was?

25 A. Yes.

1 Q. How would you figure it out?

2 A. I would ask Dr. Patwardhan what the drug was and where  
3 to store it.

4 Q. With respect to the drug Docetax, how would you refer to  
5 that drug?

6 A. Taxotere.

7 Q. Now, turning back to the charge slip that has already  
8 been entered into evidence, Exhibit 112, could you please  
9 show the jury where you would indicate that this drug had  
10 been administered?

11 A. (The witness complies).

12 MR. WIDMAN: Please let the record reflect that she  
13 checked off next to the words, Taxotere, 20 milligrams,  
14 parentheses, Docetaxel.

15 BY MR. WIDMAN:

16 Q. Ms. Franco, did you learn at some point that Jessica  
17 Young was bringing drugs into the office from Honduras?

18 A. Yes.

19 Q. And how often would she make trips?

20 A. She would go about three times a year.

21 Q. Could you describe how she brought them back?

22 A. She would bring them back in gift boxes, like Nordstrom  
23 gift boxes, or Macy's bags.

24 Q. Was there any packaging accompanying the drugs?

25 A. No.

1 Q. And you said gift boxes. Can you describe what the  
2 boxes look like?

3 A. It looked like a present with a ribbon on it.

4 Q. Would there be any tissue paper or other packaging of  
5 that sort?

6 A. Yes, tissue paper.

7 Q. Thank you. Did you ever see Dr. Patwardhan mixing drugs  
8 that were brought into the office from Honduras?

9 A. Yes.

10 Q. Was there ever a time when you would clear off the  
11 counter drugs from Honduras?

12 A. Yes.

13 Q. How much supply of drugs from Honduras would be brought  
14 in typically?

15 A. Maybe about twenty, twenty or thirty.

16 Q. Twenty or thirty --

17 A. Vials of chemotherapy.

18 Q. And how long would that last? Let me rephrase the  
19 question.

20 How long would that quantity supply the medical  
21 office?

22 A. About two months.

23 Q. Was any effort made to keep the drugs cold?

24 A. No.

25 Q. Was there any room in the boxes for ice packs or some

1 way to keep the drugs cold?

2 A. No.

3 Q. Were these drugs that ordinarily were refrigerated?

4 A. Yes.

5 Q. I would like now to show you exhibits 115 and 115A.

6 Actually, before I do that, let me ask you, did you inventory  
7 drugs that were brought in from Honduras like you explained  
8 for the drugs that came in from India?

9 A. Yes.

10 Q. Thank you. Now, I'd like you to look at Exhibits 115  
11 and 115A. What do these appear to be?

12 A. The name of the medication.

13 Q. More generally, what kind of document is it?

14 A. Like an invoice that we would do ourselves with the  
15 medication that was brought in and the number of vials.

16 Q. And are these documents both in your handwriting?

17 A. Yes.

18 Q. Do your initials appear on both of these documents?

19 A. Yes.

20 MR. WIDMAN: Your Honor, the Government seeks to  
21 have these exhibits moved into evidence and published, 115  
22 and 115A.

23 THE COURT: Any objection?

24 MR. GLUCK: None, Your Honor.

25 THE COURT: Thank you. 115 and 115A are ordered

1 admitted and you may publish.

2 MR. WIDMAN: Thank you, Your Honor.

3 BY MR. WIDMAN:

4 Q. I am now placing on the overhead projector Exhibit 115.

5 Could you please explain the contents of this document to the  
6 jury?

7 A. We have the date here. And this is for Jessica, the  
8 office administrator. Here are the names of the chemotherapy  
9 medications and the quantities that were counted for.

10 Q. And can you please point out your initials?

11 A. (The witness complies).

12 Q. And there's another set of initials here. Do you see  
13 that?

14 A. Yes.

15 Q. Do you know whose initials those may be?

16 A. Jessica Young.

17 Q. Thank you. Were there ever times when you were  
18 preparing this kind of inventory that you didn't know what  
19 kind of drug it was?

20 A. Yes.

21 Q. And how would you figure it out?

22 A. I would ask Dr. Patwardhan.

23 Q. Let's say, for example -- well, let me ask you this: Do  
24 you remember a drug called Farmorubicina?

25 A. Yes.

1 Q. How would you list that on the inventory?

2 A. Farmorubicina.

3 Q. Okay. I'm now going to go back to what has already been  
4 entered into evidence as Exhibit 112 and place that on the  
5 overhead projector. Do you see that on this form? I realize  
6 it's actually quite difficult to see.

7 A. Right there.

8 Q. So if you were to administer the medication  
9 Farmorubicina, you would mark indicated where it says -- I  
10 already lost it. Oh, there it is, okay. Doxorubicin. I'm  
11 sorry. Can you please underline it again. Epirubicin. It's  
12 a couple below Ellence, Epirubicin, for the record.

13 A. Yes.

14 Q. Changing gears a little here, were you ever present when  
15 Dr. Patwardhan would communicate with his patients about the  
16 course of treatment they were receiving?

17 A. Yes.

18 Q. Did Dr. Patwardhan ever tell them that he was  
19 administering them drugs that had been brought into the  
20 country from India?

21 A. No.

22 Q. Did Dr. Patwardhan ever tell them that he was  
23 administering them drugs that he brought into the country --  
24 excuse me, strike that.

25 Did Dr. Patwardhan ever tell them that he was



1 administering them drugs that had been brought into the  
2 country from Honduras?

3 A. No.

4 Q. Did Dr. Patwardhan ever tell them that he was  
5 administering them drugs that were not approved by the FDA?

6 A. No.

7 Q. Did Dr. Patwardhan ever refer to the drugs by their  
8 Indian trade names?

9 A. No.

10 Q. Was there ever a time when a patient would ask  
11 Dr. Patwardhan or his staff to write down the names of the  
12 drugs, chemotherapy drugs, they were receiving?

13 A. Yes.

14 Q. And approximately how often would that happen?

15 A. Not that often, but it did happen.

16 Q. Were you ever involved in providing such a list?

17 A. Yes.

18 Q. Did you ever write down Indian trade names?

19 A. No.

20 Q. Now, I believe you mentioned at the outset that one of  
21 your responsibilities was ordering drugs. Do you remember  
22 that or have you testified to that?

23 A. Yes.

24 Q. How would you go about carrying out that responsibility?

25 A. We would -- there was a white board in the hallway and

1 normally we would write the names of the medications that we  
2 are running low on. And we would call OTN and --

3 Q. Let me stop you there. What is OTN?

4 A. OTN is a distributor. It is a company that distributes  
5 chemo medications.

6 Q. Was there any other company that you ever purchased  
7 medications from?

8 A. NSS.

9 Q. Did you ever speak with Dr. Patwardhan regarding the  
10 current supply of chemotherapy medications?

11 A. Yes.

12 Q. Did he ever mention purchases of drugs from India?

13 A. Yes.

14 Q. What would he say?

15 A. When he was going to go on a trip he would say, "Don't  
16 order this because I'm going to bring it home from India."

17 Q. When you say, "Don't order this," what do you mean?

18 A. Like, for example, Taxotere, Camptosar.

19 Q. Did you understand "Don't order this" to mean from a  
20 particular place?

21 A. Not to order it from OTN and NSS.

22 Q. Did Dr. Patwardhan ever indicate why he was purchasing  
23 drugs in India instead of in the United States?

24 A. Yes.

25 Q. What was that reason?

1 A. He told me that it was cheaper to buy them over there.

2 Q. Would you ever speak with -- excuse me, strike that.

3 Approximately what percentage of the medications  
4 that were used in the office, chemotherapy medications, were  
5 brought into the office from Honduras or India?

6 A. About 90 percent.

7 Q. Now, you mentioned OTN and NSS. When you ordered  
8 medications from OTN or NSS, how were they sent to the  
9 office?

10 A. In cardboard boxes with "Fragile" on it and they were in  
11 ice.

12 Q. How were they transported?

13 A. By UPS or FedEx.

14 Q. For those drugs that are supposed to be refrigerated,  
15 were they refrigerated?

16 A. Yes.

17 Q. How were they refrigerated?

18 A. With ice packs and it came in a Styrofoam container.

19 Q. And once they reached the office, was there any  
20 confusion about what kind of drugs they were?

21 A. No.

22 Q. When you ordered drugs from OTN or NSS, did anyone ever  
23 physically go to OTN or NSS, pick up the drugs and bring them  
24 back into the office?

25 A. No.

1 Q. During the time that you worked with Dr. Patwardhan did  
2 you ever get the impression that he was cost conscious?

3 A. Yes.

4 Q. What led you to that? What was your impression?

5 A. By him saying that the drugs over in India were cheaper.  
6 And sometimes he would mention that there was no money coming  
7 in, that the Chino office was in the red.

8 Q. What do you mean by, "The Chino office was in the red"?

9 A. In the red was it's not making any money, so the Upland  
10 office has to put money to the Chino office to cover the  
11 expenses.

12 Q. Was there any discussion regarding the number of  
13 patients he was seeing on any particular day?

14 A. Can you repeat that?

15 Q. Was there any discussions regarding the number of  
16 patients he was seeing in any particular day?

17 MR. GLUCK: Objection, the questions are leading.

18 THE COURT: Overruled.

19 THE WITNESS: Yes.

20 BY MR. WIDMAN:

21 Q. What kind of discussion?

22 A. He would tell the receptionist or the medical assistants  
23 to call patients to come in. He wanted to see about  
24 40 patients a day at least.

25 Q. And if he wasn't seeing that number of patients a day,

1 what would happen or what would he say?

2 A. He would tell us to call patients to come in, or if the  
3 patient didn't show up, to call them to come in.

4 Q. Switching gears, do you recall being involved in the  
5 treatment of a patient called Veronica Lin?

6 A. Yes.

7 Q. Was any family member of Ms. Lin involved in the medical  
8 treatments?

9 A. Yes.

10 Q. Do you recall her name or his name?

11 A. I believe it was Katherine.

12 Q. Thank you. What kind of medication was given to  
13 Ms. Lin?

14 A. She took Neulasta. It's an injectable.

15 Q. I would like to show you Exhibits 127, 127A, and 127B.  
16 Please just take a look at them for yourself. Could you tell  
17 us what's in these pictures?

18 A. It's Neulasta. It's the injection.

19 Q. Was that the same kind of medication that was given to  
20 Ms. Lin?

21 A. Yes.

22 MR. WIDMAN: Your Honor, the Government seeks to  
23 have Exhibits 127, 127A and B entered into evidence and  
24 published.

25 THE COURT: Any objection?

1 MR. GLUCK: None, Your Honor.

2 THE COURT: 127A and B are ordered admitted and you  
3 may publish.

4 MR. WIDMAN: Thank you.

5 BY MR. WIDMAN:

6 Q. I'm placing on the overhead projector Exhibit 127A.

7 Could you please tell us what we see here?

8 A. This is, I believe, in Indian writing or Hindu, I'm not  
9 sure, but this is Neulasta in USA, I guess USA brand.

10 Q. Would this be -- let me ask you this: I'm going to take  
11 this off the overhead projector. The Indian injectable that  
12 we just looked at, was that given to Ms. Lin to take home for  
13 her treatment?

14 A. Yes.

15 Q. Were there any concerns ever raised from the patient or  
16 the patient's family about that?

17 A. Yes.

18 Q. Can you please tell us about that?

19 A. The patient's daughter, her name is Katherine, she  
20 called the office one time when she got this injection and  
21 she was concerned about the injection because it wasn't the  
22 same injection that was given to her previous. So we told  
23 Dr. Patwardhan that she was concerned about the injection,  
24 and Dr. Patwardhan told me to tell her to bring back the  
25 injection and we would give her another injection.

1 Q. Let me ask you this, Ms. Franco: Did you receive any  
2 guidance from Dr. Patwardhan about this incident in terms of  
3 future conduct?

4 A. Yes.

5 Q. What was that guidance?

6 A. He told all the medical assistants not to give those  
7 injections to the patient's for home use, to use those for  
8 the office use.

9 Q. Switching gears now.

10 THE COURT: Is now a good breaking point?

11 MR. WIDMAN: Yes, Your Honor.

12 THE COURT: All right. Ladies and gentlemen, we  
13 will adjourn, as far as you're concerned, this afternoon and  
14 we will resume tomorrow morning at 9:00 with you. You can  
15 gather in the jury room any time after 8:30. Fresh coffee is  
16 served at 8:30. My assistant, I don't know if you've met her  
17 yet, she's unforgettable, so you'll know when you've met her,  
18 and she makes a mean cup of coffee. She will have coffee  
19 ready for you at 8:30. And we will start promptly at 9:00  
20 tomorrow morning.

21 Thank you so much for your work here today.  
22 Remember, don't discuss the case with anyone, apart from  
23 telling family members or whomever you may see this evening  
24 that you've been seated as a juror on a case in the U.S.  
25 District Court. That's all you should really say. And don't

1 do any research in any fashion. Don't read any newspaper  
2 articles, listen or watch any media reports about the case,  
3 if there are any. Don't communicate in any fashion, e-mail,  
4 blogging, all the other things I mentioned, Twittering,  
5 anything of that nature or of any nature of any sort. Don't  
6 communicate in any fashion. Do not make up your minds about  
7 the case or any issue involved in this case, because you  
8 haven't heard all of the evidence, of course.

9 Thank you, ladies and gentlemen. We'll see you  
10 tomorrow morning at 9:00.

11 And you may step down.

12 (The jury has now exited the courtroom)

13 THE COURT: We are on the record outside the  
14 presence of all members of the jury.

15 You may be seated. A couple of housekeeping  
16 matters to take up quickly.

17 You will continue with Ms. Franco in the morning?

18 MR. WIDMAN: Yes, Your Honor.

19 THE COURT: How much longer do you think your  
20 direct will be?

21 MR. WIDMAN: One moment, please, so I can just  
22 check over my notes. I estimate about 45 minutes.

23 THE COURT: How long do you estimate for  
24 cross-examination, Mr. Gluck?

25 MR. GLUCK: I would guess about an hour.



1 THE COURT: The next witness?

2 MR. WIDMAN: The next witness we expect is going to  
3 be Mindy Funk.

4 THE COURT: How long do you think her direct will  
5 be?

6 MR. BEHNKE: Her direct will be no longer than an  
7 hour. I expect shorter than that, maybe more in the  
8 neighborhood of 40, 45 minutes.

9 THE COURT: All right. And then after that?

10 MR. WIDMAN: Jessica Perez, Your Honor.

11 THE COURT: And then?

12 MR. WIDMAN: Kathy Walton, Your Honor.

13 THE COURT: It's not the lineup that is causing me  
14 to tear up, I'm sorry, it's just my allergies.

15 If we need another witness, who would the next one  
16 be?

17 MR. WIDMAN: If there is a fourth witness in  
18 addition to Ms. Franco, we expect that it would be Dr. Lee.  
19 And also, to make clear, the order of the first two, we're  
20 not sure which is going to go first or second.

21 THE COURT: You mean as to Funk or Perez?

22 MR. WIDMAN: Yes, Your Honor.

23 THE COURT: All right. A couple of other issues to  
24 take up first. One of the things we were talking about late  
25 yesterday, and that is the Grand Jury testimony of

1 Ms. Young. You know, Ms. Young testified on -- do you all  
2 have copies? Is this the only copy you have?

3 MR. WIDMAN: It's the only copy I have with me.  
4 Obviously, I'm very familiar with it and I believe defense  
5 counsel has a different copy.

6 THE COURT: Do you have a copy, Mr. Gluck?

7 MR. GLUCK: I can as soon as I get this thing to  
8 wake up.

9 THE COURT: We were talking late yesterday about  
10 the differing perspectives that counsel have regarding her  
11 Grand Jury testimony. I think there were at least two  
12 places -- maybe there were more, but there were two places  
13 where she testified with regard to her understanding of  
14 whether bringing the drugs into the country from Honduras was  
15 unlawful. One was on page 11 of the testimony. I think this  
16 might have been what you read yesterday into the record.

17 Are you still waiting for it to warm up?

18 MR. GLUCK: No, I've got it. Actually, Your Honor  
19 is correct. It is on page 11. It was a question by  
20 Mr. Widman. The one I read yesterday was a question by the  
21 Grand Juror which was on the same -- I mean, it's the same  
22 thing, but this is not the one I read.

23 THE COURT: All right. On page 11 she said -- the  
24 question was: When you brought drugs into the country, you  
25 didn't know it was illegal; is that right?

1           Answer: That's correct.

2           That's near the bottom of the page on page 11.

3           On page 13 -- and this is, again, in answer to a  
4 question by Mr. Widman -- the question is asking: At the  
5 time of the initial conversation with Dr. Patwardhan, like  
6 you told us, the initial conversation, you knew at that point  
7 that it wasn't right to bring in drugs from overseas; is that  
8 right?

9           Answer: Correct.

10          Question: And that's why you were unwilling to  
11 help him in that regard; is that right?

12          Answer: Correct.

13          Then on page 21: And at that time that you brought  
14 the drugs in, you didn't know there was anything illegal  
15 about doing so; is that right?

16          Answer: That is correct.

17          So there are differing answers to this question.

18          MR. WIDMAN: Your Honor --

19          THE COURT: Depending on -- she's talking about  
20 different time periods.

21          MR. GLUCK: She is also talking about different  
22 things, Your Honor. If you look at page 13, the  
23 discussion, the colloquy, begins actually on page 12.

24          THE COURT: Right.

25          MR. GLUCK: Where he says -- I'm sorry, where she

1 discusses that she doesn't want to -- well, it actually  
2 starts with, did you learn that Dr. Mhaskar did, in fact, buy  
3 drugs in India? I'm sorry. I'm backing up here.

4 On page 11 the chain of questions begins.

5 THE COURT: About Dr. Mhaskar?

6 MR. GLUCK: Exactly. And what she's saying is she  
7 refused to help Dr. Patwardhan. She will testify that at  
8 some point, after this attorney/client conversation,  
9 Dr. Patwardhan asked her to ask Dr. Mhaskar to bring medicine  
10 from India and to tell Dr. Mhaskar that she was the one that  
11 wanted Dr. Mhaskar to do that. And she refused to do that.  
12 She never did that. She did pay for the trip and whatever,  
13 but that's something else, but she never did that.

14 And so the question of, the reason you did that is  
15 because -- I'm sorry, the reason you didn't do that, the  
16 reason you refused, because at that point you knew it was  
17 wrong, was her explaining why after March 2008 she refused to  
18 tell Dr. Mhaskar that she was the one asking Dr. Mhaskar to  
19 bring the drugs into the country. But she is consistent that  
20 for all the times she actually made trips, meaning Jessica  
21 Young made trips, because her trips ended in February 2008,  
22 all the times she made trips, she's consistent throughout,  
23 both answering Mr. Widman as well as answering the Grand  
24 Juror, that when she did it, she thought it was legal.

25 The only thing she's saying she refused to do,

1 because at that point she knew that it was wrong, is talk to  
2 Dr. Mhaskar about Dr. Mhaskar bringing it in. This goes back  
3 to our point yesterday, which is, why does she know it's  
4 wrong. According to her, because by that point she'd talked  
5 to a lawyer.

6 THE COURT: On page 11, right after the discussion  
7 about Dr. Mhaskar, the question is, to backtrack when you  
8 brought drugs back into the country, so your point is --

9 MR. GLUCK: It is backtracking chronologically.  
10 She did it between 2004 and February 2008. Then they talk  
11 about why she did what she did after March of 2008.

12 THE COURT: All right. Do you have anything to add  
13 on that point?

14 MR. WIDMAN: Yes, Your Honor, we do have one thing  
15 to add. If you'd just give me one moment, Your Honor.

16 Yes, Your Honor. Essentially, the point that we  
17 want to make is, as we said yesterday, I'm going to restate  
18 something I said yesterday and then give the new point after  
19 just for context. What I said yesterday essentially was,  
20 once you remove the original reference to attorney, there's  
21 no inference later that, oh, someone must have talked to an  
22 attorney and so forth and so on. And then defense counsel  
23 said, well, that would put him in the awkward position of  
24 having to not be able to ask, you know, why did you think  
25 that. And the Government submits that --

1 THE COURT: Or not being able to cross-examine.

2 MR. WIDMAN: And the Government submits that he is  
3 able to cross-examine if he wants to, if he wants to waive  
4 the privilege, but it's not a situation where he's not  
5 permitted to, where he's not allowed to or you would tell  
6 him, "Please stop, counsel."

7 THE COURT: Well, no, she consulted her private  
8 attorney, didn't she?

9 MR. GLUCK: No, Your Honor. She never had a  
10 private attorney until after the search, which was in July.

11 MR. WIDMAN: Your Honor, if I may clarify the time  
12 frame, I'm confident defense counsel would agree with this.

13 THE COURT: I think I understand the time frame.  
14 At that point she consulted Mr. --

15 MR. GLUCK: Fergie. Exactly. Her position is that  
16 she, through Dr. Patwardhan, obtained the advice of  
17 Mr. Fergie.

18 THE COURT: No, that's your position.

19 MR. GLUCK: No, that's Ms. Young's position.

20 MR. WIDMAN: She said to Dr. Patwardhan, you need  
21 to talk to a lawyer. Dr. Patwardhan learned from the lawyer  
22 that it was illegal, told Ms. Young that, and here we are.

23 THE COURT: Well, it's your position that it's a  
24 corporate privilege.

25 MR. GLUCK: Correct. The only lawyer that

1 Ms. Young has individually is Mr. Miller who is retained like  
2 from the 31st of July. I know this goes without saying, but  
3 we, of course, dispute her characterization of what happened  
4 here, but because it's privileged we don't need to go there.

5 The point is, this evidence -- and I was really  
6 thinking about this last night, because other than knowing  
7 something is wrong here, in terms of the framework in the  
8 rules, the problem is there are only two possible options in  
9 terms of this evidence having any or drawing any inference  
10 from this evidence. Either it's inadmissible under 501 as  
11 attorney/client privilege, or it's inadmissible under 403 as  
12 being entirely misleading, because we know that the only true  
13 inference that could be drawn from here goes right through  
14 the privilege. If we cut that out, then all we're doing is  
15 throwing something to the jury that causes them to speculate  
16 about, well, gee, if Ms. Young, who is not a doctor, was able  
17 to educate herself on this point in March of 2008, it's a lot  
18 less likely that Dr. Patwardhan didn't know about it then.

19 THE COURT: Now, the jury -- counsel can argue -- I  
20 am still not inclined to let the Government ask her why, but  
21 the Government is free to argue at the end of the case that  
22 her actions in the way that she brought the drugs in, the  
23 medications in, to use their language, hiding them and  
24 putting them in a department store gift box and so forth,  
25 shows that she didn't want to see -- some consciousness that

1 bringing them in was not aboveboard or was wrong and that she  
2 was trying to conceal them. And they can argue that. That's  
3 free to be argued. That's circumstantial evidence. And they  
4 can argue all the circumstantial. They can ask her about  
5 that. They can ask her why she did all those things at that  
6 time.

7 MR. GLUCK: Absolutely.

8 THE COURT: Like I said, I don't want to tell -- I  
9 don't need to do that. Certainly neither side needs me to  
10 say. But the question as to why she stopped, my ruling  
11 stands on that.

12 MR. WIDMAN: Thank you, Your Honor. I just want to  
13 make one other point that I think really underlies this whole  
14 thing, which is if the defense's position is that the advice  
15 was never given, then why have we been litigating whether  
16 this communication is privileged or not.

17 THE COURT: I don't think that's their position.  
18 That wasn't my understanding.

19 MR. GLUCK: First of all, it's simply not the rule,  
20 that I need to waive privilege unless you know exactly what  
21 the attorney said.

22 THE COURT: I don't need to hear any more  
23 argument. In the interest of time, I understand the issue  
24 and I've heard both sides.

25 Let's see. The other issue as to the -- I have the



1 case law and so forth right here. The issue about who has  
2 the burden of proof about the statutory exception -- now, let  
3 me just say while I'm waiting for that, as a piece of trial  
4 advocacy advice I will give to both sides, but 75 percent to  
5 the defense, it does not cure the argumentative nature of an  
6 opening statement to insert the words, "The evidence will  
7 show that" before you make an argumentative -- before you  
8 argue in opening statement.

9 MR. GLUCK: Thank you, Your Honor.

10 THE COURT: Thank you. There was a bit of argument  
11 that both sides did, you know, but it was more than a bit on  
12 your side.

13 MR. GLUCK: I appreciate any trial advocacy advice  
14 the Court is willing to give.

15 THE COURT: Next time you try a case in front of  
16 me, on opening I'll be a little bit more on guard.

17 MR. GLUCK: I'm fairly warned.

18 THE COURT: All right. The instruction that's at  
19 issue here -- I think I went to that same class and heard  
20 that same piece of advice about starting off with, "The  
21 evidence will show that." And, of course, one's perspective  
22 changes.

23 All right. It's Government's proposed instruction  
24 No. 4 which is on page 9 of what was called the joint  
25 proposed jury instructions, but it's behind tab A, page 9,

1     because it is one of the not so joint ones. All right.

2                 So the issue is, as I understand the parties'  
3     positions here, who has the burden of proof of showing the  
4     statutory exception applies. There's no Ninth Circuit case  
5     that we've been able to find or, apparently, that the parties  
6     have been able to find. And although, as I understand it,  
7     the defendant's position is that, in general, that the burden  
8     of proof is on the Government to prove the elements, this  
9     issue does not really --

10                MR. BEHNKE: I'm sorry, Your Honor. In  
11     anticipation of arguing about this earlier today, I did some  
12     additional research and have a case to cite to the Court and  
13     to defense. I apologize. I was in a hurry. I didn't bring  
14     multiple copies to hand out. But there's another case. It  
15     is certainly not an FDA case, but it has to do with  
16     exemptions concerning crimes that occur on Native American  
17     land. And the Ninth Circuit also said in that case that, you  
18     know, statutory exemptions, in that context defense has the  
19     burden of producing evidence if the exception applies, and  
20     then the Government at that point would bear the burden of  
21     proving beyond a reasonable doubt the nonexistence.

22                THE COURT: In other words, it's a defense.

23                MR. BEHNKE: Yes, Your Honor.

24                THE COURT: It's a defense which the defendant has  
25     the burden of establishing?

1 MR. BEHNKE: Yes, Your Honor.

2 THE COURT: What's the citation to the case?

3 MR. BEHNKE: It's United States v. Bruce,  
4 394 F.3d 1215.

5 THE COURT: All right. I'm inclined, after reading  
6 the cases that were cited, I think it's an Eleventh Circuit  
7 case, which is United States v. Hill, which is very helpful,  
8 it's not a Ninth Circuit case, but to find that the  
9 instruction that the Government has proposed appropriately  
10 assigns the burden; that is, that the defense has the burden  
11 of showing that it falls within the statutory exception. And  
12 if it has done so, then the burden shifts to show that the  
13 exception does not apply, but not until it has met -- the  
14 defense has the initial burden, as it would be a defense.

15 So I'm inclined to give the instruction that the  
16 Government has proposed.

17 MR. GLUCK: Your Honor, may we just take a look at  
18 the case and raise it again if we are --

19 THE COURT: Certainly.

20 MR. BEHNKE: Just to clarify, Your Honor, the  
21 Government apologizes for the way that this was all crafted,  
22 but at the end of the case if there has been no evidence of  
23 any exemptions --

24 THE COURT: Then you would object to having that  
25 defense?

1           MR. BEHNKE: We would withdraw that objection at  
2 that point, the definition -- the instruction defining the  
3 exemptions.

4           THE COURT: You would withdraw this instruction?

5           MR. BEHNKE: That proposed instruction.

6           THE COURT: Exactly. Not your objection, but the  
7 instruction.

8           MR. BEHNKE: Yes, Your Honor.

9           THE COURT: I'm so easily confused. Don't make it  
10 any worse. Thank you. I understand.

11           I think that my intended ruling should help you  
12 about the witness that you're going to put on.

13           MR. BEHNKE: Yes, Your Honor.

14           THE COURT: Thank you. I'll see you tomorrow  
15 morning.

16           MR. GLUCK: May I ask one question?

17           THE COURT: Certainly.

18           MR. GLUCK: Just as a practical matter with respect  
19 to Dr. Lee, Dr. Lee is -- I know subject or consistent with  
20 the Court's ruling about what he can testify about, he is  
21 going to be talking somewhat about the FDA regulatory scheme,  
22 I would like to, although, I don't know yet what, but would  
23 like to possibly use in cross-examination FDA material that's  
24 available on the FDA's Web site and things like that. In  
25 terms of requesting judicial notice to allow those things in,

1 I don't know how the Court wants to handle that.

2 THE COURT: Is it on the FDA's Web site?

3 MR. GLUCK: Yes. Printed from FDA dot gov slash  
4 whatever.

5 THE COURT: Before you give your cross-examination,  
6 you have to give the Government copies and me a copy of  
7 anything you wish the Court to take judicial notice of.

8 MR. GLUCK: That's fine. Thank you.

9 (Proceedings adjourned)

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C E R T I F I C A T E

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I hereby certify that pursuant to Section 753, Title 28, United States Code, the foregoing is a true and accurate transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

PHYLLIS A. PRESTON, CSR  
Federal Official Court Reporter  
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